EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:Master File No. :2:12-MD-02327 : :MDL No. 2327
THIS DOCUMENT RELATES TO THE CASES LISTED BELOW	:JOSEPH R. GOODWIN :U.S. DISTRICT JUDGE

Mullins, et al. v. Ethicon, Inc., et al.	2:12-cv-02952
Sprout, et al. v. Ethicon, Inc., et al.	2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.	2:12-cv-09765
Daniel, et al. v. Ethicon, Inc., et al.	2:13-cv-02565
Dillon, et al. v. Ethicon, Inc., et al.	2:13-cv-02919
Webb, et al. v. Ethicon, Inc., et al.	2:13-cv-04517
Martinez v. Ethicon, Inc., et al.	2:13-cv-04730
McIntyre, et al. v. Ethicon, Inc., et al.	2:13-cv-07283
Oxley v. Ethicon, Inc., et al.	2:13-cv-10150
Atkins, et al. v. Ethicon, Inc., et al.	2:13-cv-11022
Garcia v. Ethicon, Inc., et al.	2:13-cv-14355
Lowe v. Ethicon, Inc., et al.	2:13-cv-14718
Dameron, et al. v. Ethicon, Inc., et al.	2:13-cv-14799
Vanbuskir, et al. v. Ethicon, Inc., et al.	2:13-cv-16183

SEPTEMBER 29, 2015

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CAPTION CONTINUED:
Mullens, et al. v. Ethicon, Inc., et al. 2:13-cv-16564
Shears, et al. v. Ethicon, Inc., et al. 2:13-cv-17012
Javins, et al. v. Ethicon, Inc., et al. 2:13-cv-18479
Barr, et al. v. Ethicon, Inc., et al. 2:13-cv-22606
Lambert v. Ethicon, Inc., et al. 2:13-cv-24393
Cook v. Ethicon, Inc., et al. 2:13-CV-29260
Stevens v. Ethicon, Inc., et al. 2:13-cv-29918
Harmon v. Ethicon, Inc., et al. 2:13-cv-31818
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Miller v. Ethicon, Inc., et al. 2:13-cv-32627
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Jones, et al. v. Ethicon, Inc., et al. 2:14-cv-09517
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Gillum, et al. v. Ethicon, Inc., et al. 2:14-cv-12756
Whisner, et al. v. Ethicon, Inc., et al. 2:14-cv-13023
Tomblin v. Ethicon, Inc., et al. 2:14-cv-14664
Schepleng v. Ethicon, Inc., et al. 2:14-cv-16061
Tyler, et al. v. Ethicon, Inc., et al. 2:14-cv-19110
Kelly, et al. v. Ethicon, Inc., et al. 2:14-cv-22079
Lundell v. Ethicon, Inc., et al. 2:14-cv-24911
Cheshire, et al. v. Ethicon, Inc., et al. 2:14-cv-24999
Burgoyne, et al., v. Ethicon, Inc., et al. 2:14-cv-28620
Bennett, et al., v. Ethicon, Inc., et al. 2:14-cv-29624

SEPTEMBER 29, 2015

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Videotaped Deposition of ROGER McLENDON, M.D., called for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before KAREN K. KIDWELL, RMR, CRR, Notary Public for the State of North Carolina, at Duke University Medical Center, Duke Clinics/South, 200 Trent Drive, Room 3114, Durham, North Carolina, on September 29, 2015, at 2:02 p.m.

APPEARANCES:

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ALSO PRESENT: Len Harris, Videographer

I N D E X

(No exhibits marked.)

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TUESDAY, SEPTEMBER 29, 2015, DURHAM, NORTH CAROLINA
PROCEEDINGS
-oOo-
VIDEOGRAPHER: We are now on the record. My name is Len Harris. I am a videographer for Golkow Technologies. Today's date is September 29th, 2015, and the time is approximately 2:02 p.m.
This video deposition is being held in Durham, North Carolina in regards to Ethicon, Incorporated, Pelvic Repair System Products Liability Litigation. This case relates to Mullins, et al, versus Ethicon, Incorporated, et al. Case Number is 2:12-CV-02952. Master File Number is 2:12-MD-02327. MDL Number is 2327. This case is being held in the United States District Court for the Southern District of West Virginia, Charleston Division.
The deponent is Roger McLendon, M.D.
Counsel, would you please identify yourselves.
MR. MONSOUR: Doug Monsour for the plaintiff, along with Katy Krottinger and Chapman Bauerlein.
MR. VOUDOURIS: Peter Voudouris on behalf

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of Defendant Ethicon.
MR. THOMAS: David Thomas for Defendants.
VIDEOGRAPHER: The court reporter is Karen Kidwell and will now swear in the witness.
ROGER MCLENDON, M.D.
being first duly sworn, testified as follows:
VIDEOGRAPHER: Please continue.
EXAMINATION
BY MR. MONSOUR:
Q. All right. Good afternoon, Dr. McLendon. How are you?
A. I'm well. Good afternoon, sir.
Q. I'm going to try and get through this as quickly as I can. It's going to take a little while. What I would tell you is if you need to take a break or something, I can't see you, so just speak up or tell Dave or Peter that you want to take a break, and it's not a big deal. I would just ask that you finish answering my question. Is that okay?
A. Yes, sir.
Q. And then also, if I ask you something you don't understand, just ask me to rephrase it, and I'll do that. Okay?
A. Yes, sir. Can you hear me all right?
Q. Yeah, I can hear you fine. Can you hear

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me?
A. Yes, sir.
Q. Okay. Dr. McLendon, what kind of a doctor are you?
A. I'm a board-certified anatomic pathologist and neuropathologist.
Q. On a typical given day, what do you do?
A. My diagnostic clinical responsibilities are diagnostic neuropathology.
Q. And what is -- for those of us that don't practice neuropathology, tell me what a neuropathologist does.
A. Neuropathology is the study of the brain, the spinal cord, its nerves, the coverings of these tissues as well as their end targets. So my job is to examine tissues, whether they be nerve or spinal cord or brain tissue for evidence of disease. I also look at muscle and peripheral nerve.
Q. Do you -- have you ever been a pathologist that's looked at specimens from the vaginal area?
A. My job as neuropathology is to examine nerves and tissues wherever they may be. I have many years ago routinely looked at vaginal tissue, and now I will look at tissues for nerve damage, diseases of nerve, wherever they may come from in the body.

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Q. Okay. So -- so if I understand you right, as a neuropathologist, you look at nerves all over the body, wherever they may be?
A. That's correct.
Q. Okay. Do you -- have you ever looked at a transvaginal mesh specimen?
A. Before? No, sir.
Q. I didn't hear you.
A. No, sir.
Q. Have you ever looked at a TVT specimen?
A. Only as my job as the Director of the Surgical Pathology Archives. I'm the Director of Surgical Pathology here, and a few of these slings have -- are stored. And as the keeper of the archives, I am responsible for dispensing them, so I have visually looked at one or two.
Q. Okay. And when you talk about visually looking at them, I'm talking about as a neuropathologist actually examining them with the microscope or however you do it, have you actually looked at them that way?
A. No, sir.
Q. Is it fair to say that -- with that in mind, is it fair to say that before you were retained by Ethicon, that you really had no knowledge

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concerning looking at TVT specimens that had been removed from women?
A. I had no concern about that. I routinely look at -- at nerves that have been injured in the peripheral nervous system or -- and looked at normal healing processes, so I have fairly extensive experience of looking at nervous tissue from all over the body.
Q. No, I understand that. I understand that. I guess what I'm trying to get at, Dr. McLendon, is before being retained by Ethicon, had you ever been the pathologist that was called upon to examine a removed specimen involving a woman's vaginal tissue and transvaginal mesh?
A. Not to my recollection.
Q. Do -- are you here basically to talk primarily about how the nerves function or don't function in -- when they are entrapped in the mesh?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: I -- I'm here to talk about the neural pathology of the tissues that I've examined, and I'm also here to talk about the scientific method that Dr. Iakovlev used in examining these tissues in coming to his conclusions.

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BY MR. MONSOUR:
Q. Okay. Let me ask you a couple of other questions. Have you ever -- have you ever looked at polypropylene when it has been implanted in the human body and then it has been removed surgically? Have you ever looked at any specimens before that involve polypropylene?
A. I've looked at a lot of foreign bodies, but specifically whether it involved polypropylene, I'm not sure.
Q. Okay. Let me ask you this, when polypropylene is implanted in the human body, does it degrade?
A. I have no idea.
MR. VOUDOURIS: Objection.
BY MR. MONSOUR:
Q. I didn't hear you?
A. I have no idea.
Q. Do you believe that it would degrade?
MR. VOUDOURIS: Objection. Beyond the scope.
THE WITNESS: I haven't formed an opinion on that. I haven't been asked to and won't be offering an opinion on that.

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BY MR. MONSOUR:
Q. I understand. I'm asking you, though. Do you believe that polypropylene, once it's implanted in the human body, would degrade?
MR. VOUDOURIS: Objection. Asked and answered, Counselor. He told you he's not going to be opining on that subject.
MR. MONSOUR: He can tell me everything he wants. I'm asking him the question. I'm asking him his opinion.
MR. VOUDOURIS: Well, if he's not going to have an opinion about it at trial, that's what he's trying to tell you.
MR. MONSOUR: It doesn't matter. I'm asking my question. I want him to answer it.
MR. VOUDOURIS: Well, asked and answered. Go ahead one more time.
THE WITNESS: Yeah, I haven't been asked to form an opinion on that. I haven't formed an opinion on that. And I won't be offering one at trial.
BY MR. MONSOUR:
Q. Do you believe most likely that polypropylene would degrade once it is implanted in the human body?

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MR. VOUDOURIS: Objection. Asked and answered.
THE WITNESS: I haven't formed an opinion on that, and I won't be offering one at trial.
BY MR. MONSOUR:
Q. Well, I know you haven't formed an opinion, but I'm asking you, most likely, with your medical background, do you believe it probably would?
MR. VOUDOURIS: Objection. Asked and answered.
THE WITNESS: I haven't formed an opinion on that.
BY MR. MONSOUR:
Q. Do you -- do you believe that once these transvaginal mesh devices are implanted in the human body that a process of contraction happens?
MR. VOUDOURIS: Objection. Beyond the scope.
THE WITNESS: I don't know anything about the chemical properties of polypropylene. I haven't formed an opinion. I haven't done any research on it. I -- I won't be offering one at trial.
BY MR. MONSOUR:
Q. I'm talking more -- not necessarily about

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the chemical properties. I'm talking about the integration of scar tissue into the TVT. Do you believe that results in a mesh that is entrapped through the scar tissue?

MR. VOUDOURIS: Objection. Asked and answered. Go ahead.

THE WITNESS: It's my understanding that there are others that will be offering an opinion on this. I have not formed an opinion on that and won't be offering one at trial.

BY MR. MONSOUR:

Q. Do you believe that fibrous tissue grows into these implants once they're implanted?

MR. VOUDOURIS: Objection. Beyond the scope.

THE WITNESS: It's clear from looking at the specimens that smooth muscle fibroblast, blood vessels grow in and amongst the polypropylene implants.

BY MR. MONSOUR:

Q. Is that scar tissue?

A. That's scar tissue. That's a healing process. It's the body's reaction to this polypropylene implant.

Q. All right. So if I understand this right,

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when a TVT is implanted in the human body, scar tissue develops around and within the mesh, true?

MR. VOUDOURIS: Objection.

THE WITNESS: The body does react to the foreign body and does fulfill its mission to react to this polypropylene to -- to cure the introduced wound of a -- of the tissue -- of the space occupying polypropylene.

BY MR. MONSOUR:

Q. Does this scar tissue formation result in a contraction of the mesh?

MR. VOUDOURIS: Objection.

THE WITNESS: I'm not sure, sir. I haven't studied that.

BY MR. MONSOUR:

Q. Well, you've read several articles about mesh once it's implanted in the human body, correct?

A. That's correct.

Q. Do you believe, therefore, that contraction does take place?

MR. VOUDOURIS: Objection. Asked and answered.

THE WITNESS: I haven't seen any studies to say whether or not that it does happen. There's a lot of observational studies, reports

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about -- of scar tissue in and around these meshes, but none of them that conclusively prove that there's any contraction. There's none that conclusively prove that there's any abnormal response of the body to the implanted mesh.

BY MR. MONSOUR:

Q. All right. But I'm asking you your opinion. Do you believe that the scar tissue results in the mesh contracting?

MR. VOUDOURIS: Objection. Asked and answered. Beyond the scope.

THE WITNESS: My belief comes from the scientific method in reviewing the tissues. The scientific method does not prove any evidence of contraction or change.

BY MR. MONSOUR:

Q. So does that mean you believe it does not contract?

A. I have not been convinced from reading the papers or reviewing the slides that there's any contractions or abnormalities other than the body having any other incision at this site.

Q. Okay. Have you ever looked at a -- have you only looked at slides involving TVT, or have you looked at any slides involving pelvic organ prolapse

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implants?

A. I haven't looked at any tissues regarding pelvic organ prolapse. The only slides I've looked at belong to the five or six cases that were offered to me on whole slide image as well as glass slides, and I believe they were all TVT meshes.

Q. Okay. If the mesh -- if the mesh does contract when the scar tissue forms, is that something that you believe you should be aware of?

MR. VOUDOURIS: Objection.

THE WITNESS: Are you giving a hypothetical?

BY MR. MONSOUR:

Q. I'm asking you a question.

MR. VOUDOURIS: He asked you a question.

MR. MONSOUR: Well, I'm the questioner so . . .

MR. VOUDOURIS: Well, I understand that, Doug, but at the beginning of the deposition, you told the Doctor that if he didn't understand one of your questions, he was to speak up. And he just did.

BY MR. MONSOUR:

Q. Okay. Do you believe that if the mesh does contract as a result of scar tissue formation,

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that that's something that you should be aware of?
MR. VOUDOURIS: Objection. Form, foundation.
THE WITNESS: I believe that the normal healing process is something that I'm aware of, and contraction is a part of the normal healing process, and it makes no difference to me whether polypropylene is involved or not. It is -- the tissues I looked at were normal healing process, and so I accepted them for what they were.
BY MR. MONSOUR:
Q. When scar tissue forms, does it contain nerves?
A. It can contain nerves, yes, not necessarily.
Q. Are you -- are you generally aware of -- and I'm just trying to get an idea of what you know about this so just explain it the best way you can. Are you generally aware of the complaints that women that have TVT implanted in them, are you generally aware of the complaints that they have?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: I understand that they feel pain. I'm not -- I'm not -- I haven't been

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informed of the type or severity of pain or the localization of the pain.
BY MR. MONSOUR:
Q. Do you believe, as a neuropathologist, that a TVT sling, once it's implanted, do you believe that it could somehow cause pain in a woman?
MR. VOUDOURIS: Objection. Form, foundation.
THE WITNESS: That is a very difficult problem in -- in pain management science. There are some people that have just an abnormal response to pain regardless of what type of surgery they have. There are just some that are going to have pain.
We don't understand the cause -- causes of it. The pain continues regardless if they have nerve breaks, if they have anesthetic blockades. It's clear that there are certain people that are just predisposed to hurt related to surgery. And you can't predict which ones they are because we don't know what the pathophysiologic mechanisms for their pain mechanisms are.
BY MR. MONSOUR:
Q. Okay. I appreciate that response. But my question is a little more simple than that. My

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question is simply this, is it possible that a TVT, once it's implanted in a woman, could cause her pain?
MR. VOUDOURIS: Objection. Form, foundation.
THE WITNESS: The -- the question is so broad. You said "implanted." Implanted properly, implanted improperly or implanted with what types of surgery? There's a lot of variables that just haven't been studied.
I've looked at Dr. Iakovlev's papers and just can't come to -- there's so many variables that are in there. I agree with the paper of Dr. Blaivas, his Nature paper, that just says there's just so much we don't understand.
BY MR. MONSOUR:
Q. Well, let me -- let me ask my question again. Is it possible that a properly implanted TVT sling could cause a woman pain?
MR. VOUDOURIS: Objection. Form, foundation.
THE WITNESS: It is possible that a -- and as I have said before, it is possible that a woman with a TVT sling could experience a pain syndrome. We don't understand the issues or the causality of the pain.

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BY MR. MONSOUR:
Q. Okay. Let me ask -- let me ask the question another way. Is it possible that a woman would have a TVT sling implanted in her and it was done properly and that nerves would grow into the TVT sling? Is that possible?
MR. VOUDOURIS: Objection. Form, foundation.
THE WITNESS: All right. It is possible that the nerve will grow into the scar tissue around the sling. It won't grow into the polypropylene sling.
BY MR. MONSOUR:
Q. Is it possible that if a nerve grows into the scar tissue around the TVT sling, that through the process of contraction, that nerve could be squeezed and cause pain?
MR. VOUDOURIS: Objection. Form, foundation.
THE WITNESS: Ahh. You ask a question about what types of nerves can grow into this. And this, with the smooth muscle with the fibroblast, the vast majority of those nerves are going to be autonomic nerves or nerves that control involuntary -- involuntary contracture.

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Blood vessels, small arteries that grow into it will also carry their own innervation, and that's all autonomic. It's all involuntary.

It's -- it's clear that from the S100 stains I've looked at that there are nerve fibers in and amongst the polypropylene fibers. And it is clear that the vast, vast, vast majority of them are innervating smooth muscle from the own stains that Dr. Iakovlev provided.

BY MR. MONSOUR:

Q. Okay. Let me ask my question again because I don't think you answered.

Is it possible that a nerve could grow into the scar tissue around the TVT mesh that's implanted properly in a woman and that that nerve could be squeezed by contraction and cause the woman pain? Is it possible?

MR. VOUDOURIS: Objection. Form, foundation.

THE WITNESS: As I said, the autonomic nerves -- and I -- I didn't say it clearly, and I apologize. Thank you for giving me the opportunity to clarify.

The autonomic nerves will carry signals to contract the smooth muscle, to contract blood

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vessels. Those will not carry any pain -- pain signals back.

I didn't make it clear that pain fibers are a specific subtype of nerve fiber that scientists call the A delta and the C fibers. The C fibers are slow pain, the A delta fibers are sharp pain. There's a lot of different things that go on about this. And it is -- it is important to be able to characterize the nerve fibers. And the evidence that I saw from the slides were not able to characterize sensory pain fibers.

So is it possible for a pain fiber to grow into a scar and cause pain before it degenerates? I -- I suppose yes. But I think that you're -- what you're talking about is evident is a process where the pain fibers may or may not enter, but if they do, they're short-term and they degenerate. There's numbness, in other words. Vast majority of scars are numb.

BY MR. MONSOUR:

Q. Okay. Is it possible that there could be nerves that would grow in and around the scar tissue around a properly placed TVT that could generate pain

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long term?

MR. VOUDOURIS: Objection. Form, foundation.

THE WITNESS: The possibilities -- what you're asking is a scientific question. The science of it has not been analyzed, and it certainly hasn't been done by Dr. Iakovlev's studies or any of the studies that I've seen from his group. So the answer to that is it's -- it's unknown and unknowable.

There are a lot of other theories that do explain why people experience pain after this surgery. Even after they've had nerve sections, they still have phantom pain.

BY MR. MONSOUR:

Q. Now, you said there's several different types of nerve fibers, correct?

A. That's correct.

Q. And certain types carry painful sensations, correct?

A. The A delta and the C fibers transmit pain. They do.

Q. If an A delta or a C fiber was in the scar tissue around a TVT that was properly implanted and the scar tissue around it contracted, could that

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cause a woman pain?

MR. VOUDOURIS: Objection. Form, foundation.

THE WITNESS: That -- that's a lot of ifs for -- in your hypothetical. And I believe I've said that the science of that has not been proven.

BY MR. MONSOUR:

Q. The science of what has not been proven?

A. The question you just asked.

Q. Which part of it is unproven?

A. That was the question you asked. And I answered it, sir.

Q. No, no, no. You just said the science is unproven. I'm asking you which part is unproven?

A. The -- the distribution of A delta and C fibers is unknown in scar tissue, of the vaginal meshes, around the vaginal meshes. And whether or not they transmit pain is unknown in the scar tissue around the TVT meshes. The studies just haven't been done.

Q. Well, let me ask you this, in most implants that are implanted into the -- have you ever looked at abdominal mesh implants?

A. No, sir.

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Q. Would -- are you aware of whether or not A delta or C fibers grow into the scar tissue around abdominal mesh implants?

A. To my knowledge, that study has not been done. The science is just not there.

Q. So how do -- where would you expect the A delta and C fibers -- where would you expect them to form, around what type of an implant?

MR. VOUDOURIS: Objection. Form, foundation.

THE WITNESS: I don't know if I said that they would form. I believe what I said was that the A delta and C fibers may grow as -- grow back. But the vast majority of the -- of the fibers that we see are the autonomic fibers transmitting signals to the smooth muscle, to the blood vessels, to the glands, all the tissue around the -- the vaginal tissue that has been scarred.

I think that was a jump in logic, if I may say, in saying that I said that the A delta and C fibers grow back in every scar. I think I said that every scar -- most scars are numb. They carry no sensation; pain, temperature, touch, anything.

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BY MR. MONSOUR:

Q. Have you ever seen a scar tissue that did -- did cause pain?

MR. VOUDOURIS: Objection. Form, foundation.

MR. MONSOUR: Basis?

THE WITNESS: Asis?

MR. MONSOUR: Basis?

THE WITNESS: Pardon?

MR. MONSOUR: Basis for your objection?

THE WITNESS: Oh. I'm sorry. I don't understand what that means.

MR. VOUDOURIS: Oh, I just said form and foundation.

MR. MONSOUR: And I asked you the basis --

THE WITNESS: Oh, basis.

MR. MONSOUR: -- for your objection so if I need to, I can fix it.

MR. VOUDOURIS: Why don't you go ahead and ask your question again?

BY MR. MONSOUR:

Q. Have you ever seen a scar tissue that has caused a woman or anyone pain?

A. I have seen scars that are associated with pain, of course.

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Q. Okay. How did that happen? How did the scar cause pain or how was it associated with pain?

A. And that's what I -- I was saying, that it's unusual for certain people to have pain after post-operative surgery, chronic post-operative surgical pain, and we don't really know the mechanisms associated with that. That even -- I mean, soldiers who have their legs amputated will often feel pain in their toes. We just don't understand the -- the reason for that.

Q. Okay. The -- the pain -- well, let me start again.

If you don't know how it happens, how can you tell me that Dr. Iakovlev is wrong?

A. That's my biggest problem with Dr. Iakovlev is his scientific methodology. He's got to be able to compare his vaginal sling tissue of women who have pain against woman who have had their vaginal slings taken out with no pain.

I can -- I can draw a line for you on the wall up here and tell you it's an inch. But until you compare it to a known control, you don't know if it's an inch or not. I've got to have a known control to compare his studies against.

There are some studies that -- that

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actually look at vaginal mesh of women who have had their meshes taken out for urinary incontinence or urinary voiding dysfunction versus those who have had -- had pain issues. And unfortunately, they didn't look at nerve, but they looked at other reasons. They looked at scar tissue. They looked at inflammation. And none of them were associated with pain in those women.

In fact, the women who had no pain in voiding dysfunction, and I believe this was the Hill study, had more inflammation than the patients who had pain. They had -- they had as much scar as the women who had pain. Scar, fibrous tissue, inflammation just aren't the causes, and Dr. Iakovlev continues to persist in saying it is.

Q. Well, what could be the cause of these women's pain that have TVT implanted in them?

MR. VOUDOURIS: Objection. Form.

BY MR. MONSOUR:

Q. But let -- let me ask it this way, when these women that have TVT implanted in them say that they are in pain, do you believe they are lying?

A. Oh, no.

Q. Okay. So you believe when these women say they're suffering from pain from the TVT, that they

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are telling the truth?
A. I believe they are experiencing pain that is referenced to that area of the body just as those soldiers who have had above-the-knee amputations say they are feeling pain in their toes. They don't understand the causes of chronic post-operative surgical pain. We just don't understand it.
Q. Okay. Let me see if I understand this correctly. When women that have TVT implanted in them complain that they are having pain, you believe them, you just don't know exactly how the pain is being caused?
MR. VOUDOURIS: Objection.
THE WITNESS: Neither I nor a number of pain scientists and anesthesiologists and pain medicine docs who study this area extensively. They have looked to find it. And it's been shown that Dr. Iakovlev's theories are just not true.
BY MR. MONSOUR:
Q. Okay. Hold on. And remember, I read your report. I've never met you. You've got a lot that you know. I don't know what you know. So I'm just trying to get the basis of your opinion so I can understand what you're saying.

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A. Yes, sir.
Q. And so please -- and sometimes if I'm trying to clarify something, it's because, A, your answer to me wasn't clear, or, B, I just didn't understand it. So I want to make sure that I'm crystal clear.
A. Thank you. I apologize.
Q. No, that's okay. That's okay. I mean, you -- you do pathology every day and I do not. And so some of these things that you are intimately familiar with, I am not. So you just kind of have to bear with me a little bit. Okay?
A. Yes, sir.
Q. So here's what I want to see if I -- if I understand. And I use simple terms. I don't use medical terms. So understand that, too.
A. I will -- I will try to also use as simple as I can, sir.
Q. Okay. The women that have TVT implanted in them that complain that it is causing them pain, you believe that those women are being truthful and that they do feel pain. You're just not sure exactly how the pain is being caused. Is that a fair statement?
MR. VOUDOURIS: Objection.

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THE WITNESS: And -- and that -- I will agree with your -- with your summary of my testimony. And I will add that it's also based in scientific literature.
BY MR. MONSOUR:
Q. And what you mean when you say it's based in scientific literature is you're saying that how the pain -- you believe that the pain is there. You just don't know how it's being caused with regard to the nerves?
A. With regard --
Q. Is that right?
A. Let me -- let me see if I can simplify this as much as possible but not more so. And that is that pain is only perceived in the brain. And so there are a lot of potential areas along the nerve to the spinal cord to the brain that can be altered and still result in pain perception in the vagina. And that's why I say we don't know what is causing the pain.
The woman had surgery in this location. And you say one plus one equals two, but I'm here to tell you that that's not true, that there have been studies that suggest that this one plus one actually is a lot of other ones added to it. And you have to

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examine each individual point along the way in order to add up to the right conclusion. And Dr. Iakovlev's, his mathematics and his histologic studies are just too simple.
Q. Okay. Let me -- let me continue to try and clarify what I understand with you.
Do you believe that if a woman is experiencing pain from her TVT implant, that most likely, the pain generator comes from the area in the immediate vicinity of the TVT?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: That's -- that's what I'm trying to clarify, that that is not a -- a true conclusion. Acutely, immediately post-operatively, if she has pain, then that is a true statement. But when the nerves around the area of insertion are -- are cut, then they degenerate backwards sometimes all the way back to the spinal cord.
Acute pain is localized. Chronic pain somewhere along the multiple steps going back to the spinal cord and even going up into the brain. That's -- that's the simple part is -- is when you cut the nerve, the nerve degenerates backwards all the way to the spinal cord many

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times.
And you can have -- it's -- it's a very complex thing, but when you go look at her spinal cord, you can find the areas of the -- if you have a sensitive and long enough look, you can find the nerve fibers in the dorsal root ganglion where the sensory fibers lie, they will change as a result of this injury. So you have to understand that the -- even though the bleeding is in the vagina, even though the surgery is in the vagina, changes are occurring almost back to the spinal cord.
BY MR. MONSOUR:
Q. Yeah, but don't those result from the implantation of the TVT?
A. There seems to be a correlation.
Q. Okay. So the source would be the TVT -- the source of the pain or at least the original source of the pain would be the TVT implant?
A. That scientific --
MR. VOUDOURIS: Objection. Form.
THE WITNESS: I'm sorry. That scientific study hasn't been done.
BY MR. MONSOUR:
Q. But you believe most likely in your

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reasonable medical or reasonably certain medical opinion that that would be the case, correct?
MR. VOUDOURIS: Objection.
THE WITNESS: And I'll go back to what I said originally, and that is that there are a certain percentage of people who will have a chronic post-operative pain syndrome and we don't know the reasons for it. What I just gave you was a testable hypothesis, but I haven't done the studies nor have anybody else. And the studies have to be done in order to have a conclusion.
BY MR. MONSOUR:
Q. So -- so let me see if I understand you, Dr. McLendon. So basically what we know is -- is there's chronic pain. The source -- the initial source of the pain was the TVT. We just don't know how the pain is being transmitted to the brain long term?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: I believe we can say that we don't understand how the chronic pain comes about and we can't predict which woman will have it.

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BY MR. MONSOUR:
Q. Okay. Let me ask you this, once a woman's pain becomes chronic, does it go away on its own?
A. I don't know the answer to that, sir.
Q. Is there anything -- I mean, I guess you're probably their best nerve expert or their top nerve expert. So what you're telling me is pain involves nerves and the brain, correct?
A. That's correct.
Q. And once pain becomes chronic, is there anything that ever happens in the nerves or in the brain that would stop that pain from being chronic? In other words, make it go away?
A. That's a great question and a lot of great scientists are working to solve that problem. I don't -- when -- if they do, I don't think we understand the mechanism of why the pain went away, because if we did, we could figure that out, and that would be a major scientific medical discovery.
Q. Okay. Let me -- let me reask my question again because I think I was a little bit unclear possibly. Once pain becomes chronic, do you expect it to go away or remain?
A. I don't know the answer to that.
Q. Is it -- have you seen situations when

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you're looking at nerves where chronic pain remains forever?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: I am aware of patients who have chronic pain syndromes that last forever.
BY MR. MONSOUR:
Q. And do they last forever because whatever is happening in the nerves or whatever irritation there is to the nerves is ongoing?
A. Once again, we get back to that gray area where there's a lot of scientific pain research going into it that people just don't know the answer to.
Q. Have you ever seen anybody that's had chronic long-term pain where the pain has just gone away?
MR. VOUDOURIS: Objection.
THE WITNESS: I am aware of some, yes.
BY MR. MONSOUR:
Q. Is it infrequent?
MR. VOUDOURIS: Objection.
THE WITNESS: I don't know. You just asked me if I was aware.
BY MR. MONSOUR:
Q. Okay, okay. In those people where the pain went away, do you know what caused the pain to

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go away?
A. Of course not.
Q. Okay. And that's what you were talking about before, I believe. Is that -- is that a fair statement, Dr. McLendon?
A. That -- there's -- I mean, to answer that question, there are a lot of drug companies that are trying to figure that out because as you can imagine, that is a -- that is a very important area to relieve pain of chronic sufferers. That's a very important area of research.
Q. Are you involved in that research?
A. Not today. I have been approached by some pain doctors at Duke about getting involved, yes, sir.
Q. Okay. So -- so you have been approached to get involved in that, but you have not started, correct?
A. That's correct.
Q. Okay. Would you be working with one of the drug companies in that research?
A. I believe this is a Department of Defense funding apparatus.
Q. Okay. Let me ask you this, and I -- I want to talk about how nerves transmit pain a little

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bit, because I don't know much about this, and I'd like you to kind of teach me.
A. Yes, sir.
Q. How does -- how does a nerve -- how does a nerve become irritated or -- I don't even know if I'm using the right word, but how does the nerve become irritated to the point where it produces pain? What causes the irritation?
A. Yes, sir. That's a good question. Pain fibers have got receptors on the end of it. And you have got to stimulate the receptor in order to generate pain. There was a theory back in the early 1900s that excessive stimulation of any nerve resulted in pain, and that was disproven, I think, in the 1940s.
You can stimulate pain fibers and there's -- as you can imagine, there's a high density of pain fibers in the teeth. You can stimulate a tooth fiber and experience exquisite pain, but it has to be through a receptor. If you just touch on the nerves themselves, there's no stimulation of axonal action potentials or, you know, signals down the nerve fiber. And you need to stimulate the receptors.
Q. Is the -- is the receptor at the end of

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the nerve?
A. Yes, sir. Quite oftenly, it can be on the nerve. It can be back in the cell body.
Q. As far as pain receptors, are those at the end of the nerve or can those be along the length of the nerve?
A. It's my understanding they're all at the end of the nerve.
Q. So let's say I've got a pain receptor and the pain receptor is at the end of a nerve. If that's irritated, it will transmit pain back up the length of the nerve to the brain, correct?
A. Yes, sir.
Q. Now, if the nerve -- if I go back up, let's say one inch from the end of the nerve where the receptor is, and something irritates that -- that portion of the nerve, which is an inch away from the nerve receptor, will that cause the person pain?
MR. VOUDOURIS: Objection.
THE WITNESS: Even a millimeter away, it won't cause pain.
BY MR. MONSOUR:
Q. Okay. So the only area that can cause pain is the nerve receptor?
A. That's correct.

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Q. And --
A. It's -- may I -- if I could -- I'm sorry, sir. If I could interrupt and say, it's like your ears. Your ears have got receptors. And you can hear a signal going, but if the receptors in your ear were to go numb, you would be deaf. And those are nerve receptors there, but they're for vibration which is what a sound is.
Q. Okay. If -- so if something is rubbing against a nerve away from the receptor, it's not going to cause pain. But if it's rubbing at the receptor, it could cause pain?
A. It could cause pain. Alternatively, the most common pressure phenomenon are like the -- carpal tunnel syndrome where the hand goes numb, and those are pain fibers. As you can imagine, your hand has an exquisite number of pain fibers in them and -- but yet you get numbness in carpal tunnel syndrome.
Q. But in carpal tunnel syndrome, the nerve is being pinched at the wrist, correct?
A. That -- that's exactly correct. You asked about a millimeter, a centimeter, an inch away, that's exactly what's happening.
Q. Okay. So let me see if I understand your carpal tunnel analogy. Carpal tunnel is an

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irritation of the nerves not at the pain receptor, and it accordingly causes numbness, correct?
A. That's correct.
Q. However, if you went down to the end of your fingers where those nerves go to and I put a match under them and it transmitted the heat pain, that would be something that's affecting the pain receptor?
A. That's correct.
Q. So what we -- what we can -- what I can take from this analogy is that if we were to squeeze nerves away from the receptor, they wouldn't cause pain, but they might cause numbness?
A. That's correct.
Q. Is there any way to squeeze a nerve away from the receptor where it could cause pain?
MR. VOUDOURIS: Objection.
THE WITNESS: I'm not familiar with it, sir.
BY MR. MONSOUR:
Q. Okay. Now, again, on a subject that you're very familiar with and with which I'm very unfamiliar, nerve receptors are at the end of the nerves, but are there also nerve receptors that are along the length -- the length of the nerve in some

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nerves?
MR. VOUDOURIS: Objection.
THE WITNESS: I'm not familiar with those, sir. I think they're all at the end of the nerve terminals.
BY MR. MONSOUR:
Q. Okay. How -- if you look under a microscope, how does a nerve receptor look different than a nerve if you cut across them?
A. The -- the nerve receptor can have a lot of different appearances. In fact, it -- many of the C delta -- the C fibers and the A delta fibers can be what they call a -- a bare nerve terminal, can act as a -- a pain receptor. But it's the -- it's the specialized end that's -- that they just call a bare nerve terminal. Alternatively, they can be -- they can be quite large -- the Pacinian corpuscle can be quite large, actually, and that's a touch.
Q. So I guess what I'm getting at is, if you're looking at a -- a slide that cuts across a nerve and cuts across a receptor, if they're -- if they're cut, they look differently is what you're telling me?
A. Well, the way you do the scientific study on that is you take a section and stain it up for

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axons, for nerve fibers and just count them and -- in their nerve receptor field.
Q. You lost me there. Okay. My question is more -- is more simple. When you're looking at a slide, does a nerve receptor look different than a nerve?
A. By and large, no.
Q. So when you're looking at a slide and you say -- if we're trying to determine if there's nerve receptors which can cause pain, how can you tell whether or not the slides you're looking at is nerves or nerve receptors?
A. Because you look in the nerve terminal field and you look at the nerve, and with the nerve just stopped, then you assume that is a nerve receptor. If it continues on, then -- then you've got -- and you're looking at the appropriate stain, then you just count the number of nerve fibers in a location and compare them with known controls.
Q. Well, but here's my question, though. Most slides that you look at are pretty much 2D instead of 3D, correct?
A. That's correct.
Q. So if that's the case, how can you tell whether or not that's the ending point of the nerve

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or whether it continues on past where the -- the cutting of the tissue was?
A. The way they have solved that question scientifically and the studies that have looked at this is they just count the number of nerves inside of -- of nerves now, not Schwann cells, but looking at nerves, they just look at the number of nerves per square centimeter in that two-dimensional structure of that glass slide and then compare that to a control. This is most commonly done in diabetes.
Q. How does that counting of nerves -- how does that tell you whether or not it's nerve versus nerve receptors? Can you explain that to me?
A. Yes, sir. You -- as I said, you look into an area that has a receptor field. And you -- then you count the nerves and you just assume there's a one-to-one correlation of nerve-to-nerve receptors. So that increased density of nerve fibers compared to your controls should correlate with numbness or increased -- increased distribution or normal distribution of nerve fibers.
Q. I'm not so sure I understand what you're trying to explain.
A. Yes, sir.
Q. Could you try it again and kind of teach

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me -- how can you tell by looking at -- counting the number of nerves that some of them aren't -- some of them aren't receptors versus just the nerves that are continuing beyond the space that we're looking at?

A. All right, sir. The easiest way to think about it is I'm sitting at a table right now. And there are seven wires sitting on the floor in front of me. These wires all go to microphones that are -- let's just call these microphones receptors. We use a scientific shorthand to count those nerve terminals or those -- those lines and say, oh, I see seven in a short period of space. We -- then we do the assumption of there must be seven nerve receptors nearby. But you have to count it on an individual nerve fiber. When the nerves go -- and that's the other thing I haven't explained clearly.

When the nerves are about to terminate into a receptor, they become single individual fibers, not these bundles of fascicles that Dr. Iakovlev is showing, but individual nerve fibers that can be picked up by special stains. You count the individual small, tiny nerve fibers and assume there's a one-to-one correlation of the individual tiny nerve fibers to receptors and then compare that number to a known control.

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Q. Okay. So when you're looking at, I think you said, a square centimeter of tissue when you're looking at the nerves that are in there, if you saw some where there was just a single nerve fiber, there's a chance that that would be a nerve receptor?

MR. VOUDOURIS: Objection to form.

THE WITNESS: That is -- that is the way the scientific studies are done. There's a chance. And then you have to prove it.

BY MR. MONSOUR:

Q. Okay. And so -- all right. So let me see if I've got this right. I'm looking at a slide and I see a single nerve fiber. There is a possibility that that single nerve fiber is a pain receptor, correct?

MR. VOUDOURIS: Objection. Form. Go ahead.

THE WITNESS: The science suggests that you -- or tells you that you have to rule out autonomic nerves which can be done with other special stains. You can actually --

BY MR. MONSOUR:

Q. Wait, wait.

A. You can --

Q. I'm trying to do this one step at a time.

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A. Okay.

Q. I'm trying to do this one step at a time. So let's -- let's just knock this one out first and then we'll go to that one so -- because I'm having to wrap my arms around this.

So if we're looking at a slide and we see a single fiber nerve, it's possible that that could be a nerve receptor, correct?

MR. VOUDOURIS: Objection. Form.

THE WITNESS: It's possible that that could be a nerve receptor. It could be going to a nerve receptor, that's true.

BY MR. MONSOUR:

Q. Okay. So it could be a nerve receptor or possibly going to a nerve receptor. How would you, Dr. McLendon, try and figure out whether it's a nerve receptor or a nerve going to a nerve receptor?

A. That's -- I would figure it out by doing stains for autonomic nerves.

Q. Okay.

A. I would rule out the possibility.

Q. Okay. And what's an autonomic nerve?

A. Those are the nerves that are transmitting signals away from the spinal cord to the muscles, the arteries, the glands, those kind of things.

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Q. Okay. Autonomic nerves don't involve the sensation of pain, correct?

A. That's correct.

Q. Okay. Autonomic nerves might be the things that tell my -- my muscles to contract either voluntarily or involuntarily, correct?

A. Correct.

Q. Okay. So if you found -- how would you rule out that it was not an autonomic nerve?

A. There's a stain called a vasoactive intestinal peptide, VIP.

Q. Okay. So you would use the VIP stain, and that would tell you if it is autonomic or not, correct?

A. That would -- that would help a lot, yes, sir.

Q. Okay. So if you did the VIP stain and it said it's not an autonomic nerve, at that point in time, do you even know whether or not it is a nerve receptor or going to a nerve receptor?

A. You would have more confidence that it was a sensory nerve.

Q. Okay. Well -- okay, I get that. I get that, that it -- that you would know that it's a sensory nerve and not an autonomic nerve. But would

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you know at that point in time that it was a nerve receptor, or would it still be an open question as to whether it's a nerve receptor or a nerve that's simply going to a nerve receptor?

A. I'm not sure those studies have been done that I could reliably answer that question.

Q. Okay. So let me ask it this way. Any time we see a single nerve fiber, once we rule out that through VIP staining that it's an autonomic nerve, we know that that single nerve fiber could possibly be a pain receptor, correct?

MR. VOUDOURIS: Objection. Form.

THE WITNESS: I don't know how you know something could possibly be. I mean, knowledge is one thing. So it would -- you leave out the -- you leave in the possibility of it being a sensory fiber of some type.

BY MR. MONSOUR:

Q. Okay. So if I was looking for -- if I was trying to find pain-generating nerve receptors in slides that we could point to and say this might be a pain generator, I would want to look for single fiber nerves where we had ruled out that they were autonomic, correct?

A. That would be a great start.

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Q. Okay. Good. But the point that I think that you're trying to make is, and I want to make sure that I understand this, is that it could certainly be a pain receptor, but it might simply be the nerve that's going to the pain receptor. Am I correct with that?

A. You would be correct if it were the right size. A delta and C fibers are based on size and myelination degree.

Q. So what size would I be looking for for A delta and C fibers?

A. You would be looking for small fibers on C fibers. They are small non-myelinated. And the A deltas are small, thinly myelinated fibers. So you would barely be able to pick them up with an S100 stain.

Q. Would you pull out Dr. Iakovlev's report for me?

A. Yes, sir (Witness complies).

Q. Do you have it there?

A. Yes, sir.

Q. And let's turn to some of the photos that we're looking at --

A. Yes, sir.

Q. -- if we could. And I guess, starting on

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page 19, there are several photos of slides that Dr. Iakovlev's done. Do you see those?

A. I see Figure set 1A.

Q. Okay. Figure set 1A. In Figure set 1A or in any of the following pictures, do you see any possible nerve receptors in any of those pictures?

A. None. Because they are taken at too low of a magnification.

Q. And is that for all of the slides that -- is that for all of the slides that Dr. Iakovlev has included with his report?

A. That's correct.

Q. Okay. What magnification are these photos taken at?

A. These are anywhere from 10 to 20X. I'm sorry. From 4X to 10X it looks like, maybe even as high as 20X.

Q. Okay.

A. I -- I don't see any 40X or 100X.

Q. Okay. So Dr. Iakovlev's photos that are attached to his report go from -- in your opinion, about 4X to 20X?

A. Well, I mean, the -- it's stated in the slide caption.

Q. Okay. It looks like on page 69, is there

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one that's 100X?

A. That does appear to be one at 100X, yes, sir.

Q. Okay. What type of magnification would you need to see nerve receptors?

A. The A delta and C fibers you would probably need 40 to 100X.

Q. Okay. So if we look at the picture on page 69 that is 100X, are any of those nerves that you see -- or let me ask it this way, in the picture that's on page 69, or the pictures that are on page 69, do you see anything there that could possibly be a nerve receptor?

MR. VOUDOURIS: Objection. Form.

THE WITNESS: I -- I see no nerve -- it's the wrong stain. It's an H and E stain. I see no nerves in that tissue.

BY MR. MONSOUR:

Q. Okay. To see it, you said you'd need an S100 stain?

A. No, sir. I said he used an S100 stain which is a myelin stain. You would need a -- a nerve specific stain like a PGP 9.5 or a neurofilament protein stain.

Q. What was the last one called again, sir?

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A. Neurofilament protein.
Q. Okay. Did Dr. Iakovlev do any of those on -- on any of these slides?
A. Not to my knowledge, sir. It's my understanding that he asked one of the neuropathologists at his hospital which is the best stain to use, and they told him S100.
Q. So do you think that the neuropathologist at his hospital got that wrong?
MR. VOUDOURIS: Objection.
THE WITNESS: No, sir. That's a great stain for doing S100. I mean, S100 is a great stain for doing Schwann cells. But they -- and that shows you peripheral nerve -- the location of peripheral nerve fascicles. And I believe that was all Dr. Iakovlev was looking for.
BY MR. MONSOUR:
Q. Okay. Would you look over -- look at page 83. You see that?
A. I do.
Q. What is that?
MR. VOUDOURIS: Objection.
THE WITNESS: It looks like a polarization microscopic picture of some foreign material.

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BY MR. MONSOUR:
Q. Okay. Does it appear like it is degraded, in your opinion?
MR. VOUDOURIS: Objection. Asked and answered. Outside of the scope.
BY MR. MONSOUR:
Q. You can answer.
A. I have not looked at this before. And I'm not ready to form an opinion right now on it.
Q. Well, look at it now, if you would. And I'll give you a couple minutes.
A. I believe it would take me a while longer, sir. And I'd also like to refer to a lot of the literature. I mean, that's -- that's one of the problems I have is you can't just look at something and declare it to be that way and -- and play scientist. There's -- I mean, there's methodology that you have to follow, scientific method you have to follow in looking at something and describing it --
Q. I was just asking you if you knew what it was.
MR. VOUDOURIS: Objection. Asked and answered.
THE WITNESS: I'm answering the question.

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BY MR. MONSOUR:
Q. Some -- some people can look at something and say, this is what it is. I don't know what answer is in your head. So I'm asking the question. Okay?
A. I'm sorry to upset you, sir.
Q. I'm not upset. But you sound like you are.
A. No, sir.
Q. So on page 83, you can't tell me what those are pictures of?
MR. VOUDOURIS: Objection. Asked and answered.
THE WITNESS: If -- no, sir. I can't tell you without reading the caption. And the caption doesn't -- doesn't give me a hint.
BY MR. MONSOUR:
Q. Okay. Flip over the page to 84. Look in the top photo. Can you tell me what that is?
MR. VOUDOURIS: Objection.
THE WITNESS: It looks like a thread.
BY MR. MONSOUR:
Q. Okay. And why do you say that?
A. Because it's elongated and round.
Q. What type of thread?

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MR. VOUDOURIS: Objection.
THE WITNESS: I don't know, sir.
BY MR. MONSOUR:
Q. Okay. Look on the next page, page 85. What's that?
MR. VOUDOURIS: Objection. Form, foundation.
THE WITNESS: It's -- it -- it's got a caption that claims it to be polypropylene.
BY MR. MONSOUR:
Q. Okay. Do you know one way or another whether or not that's true?
A. I have no way of independently verifying that that's polypropylene.
Q. Okay. Have you ever done any research on how TVT acts once it's implanted in the body?
A. I mean, in the last few days, several days, I've -- I've read some literature on TVT implants and -- but not specifically looking at how it reacts with the body, no.
Q. Well, I guess -- I'm not asking if you just read up on it, but have you ever done any research into how TVT reacts once it's put into the body, you yourself?
A. No, sir.

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Q. Is it a fair statement to say that you have no idea how TVT reacts once it's put in the body?
A. I have not been asked to form an opinion on that, and I'm not going to offer one, sir.
Q. Right. Well, but I'm -- I'm asking -- I'm asking you right now. Do you have any idea how TVT reacts once it's put in the human body?
MR. VOUDOURIS: Objection. Asked and answered.
THE WITNESS: It acts as a foreign body, and there's foreign body giant cell reactions. Other than that, I have not formed any opinions on this and not come to any conclusions.
BY MR. MONSOUR:
Q. How do you know that it reacts as a foreign body and there's foreign body giant cells that form? How do you know that?
A. That's basic pathology, freshman year of medical school.
Q. Have you looked at tissues surrounding explanted medical implants before?
A. Yes, sir.
Q. Does -- does the body respond differently if the implant is inert versus noninert?

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A. You can answer that question by absorbable sutures. Yes, you do have absorbable sutures. We see that occasionally, and the body does form a foreign body giant cell reaction. It dissolves. It forms around, breaks off the segments, the pieces, and absorbs the tissue, and the giant cells move away.
Q. The giant cells move away?
A. That's correct. They -- they usually take up a perivascular location.
Q. What does it mean if the foreign body giant cells remain around an implant?
A. It means the implant persists.
Q. If a -- if an implant is 100 percent inert, does the -- do the foreign body giant cells go away?
A. It's my understanding they do not.
Q. So any time there's an implant, whether inert or not, the foreign body giant cells will be present?
A. That's correct.
Q. You used the -- the -- what was the example of the device that -- what's the name of it? That where the -- the foreign body giant cells come in and then they go away? What was that called?

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A. That's an absorbable suture.
Q. Okay. Are there other types of implants other than absorbable sutures that are not insert?
A. None come to mind right now, sir. I'm sure there are and I'm sure tonight I'll remember them and expound to my wife all about them.
Q. Okay.
VIDEOGRAPHER: Counselor?
MR. MONSOUR: That will be very interesting.
VIDEOGRAPHER: Counselor, excuse me. We have five minutes remaining on the tape.
MR. MONSOUR: Okay. Let me -- let me finish this up and then we'll -- we'll take a break.
BY MR. MONSOUR:
Q. Have you ever heard of some of the -- have you ever heard of some of the hip implants which might not be inert?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: As -- as the chief of surgical pathology here at Duke, I have a lot of hip implants sitting outside my door.
BY MR. MONSOUR:
Q. Okay. And some of those are not inert,

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correct?
MR. VOUDOURIS: Objection. Foundation.
THE WITNESS: I don't know, sir.
BY MR. MONSOUR:
Q. Have you ever seen a hip implant that wasn't inert?
MR. VOUDOURIS: Objection. Foundation.
THE WITNESS: I -- I don't know how to answer that. I mean, that's -- I haven't examined any of those tissues, sir, to my recollection.
BY MR. MONSOUR:
Q. Is it a fair statement to say that you do not know how the body would respond to a noninert implant?
MR. VOUDOURIS: Objection.
THE WITNESS: I just said that a -- a noninert such as the cat gut absorbable sutures are readily taken up. Macrophages come in. They break off pieces. You know, in a -- in laymen's terms, they break off pieces, and they absorb it. And then they go back and get some more. And they're all foreign body giant cell reactions in this.

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BY MR. MONSOUR:
Q. Is there anything that I should look for if I'm trying to establish with regard to how the body responds, what should I look for to determine if a product or an implant is degrading? Is there any response in the body which would tell you there is degradation of the implant going on?
MR. VOUDOURIS: Objection. Form, foundation. Beyond his scope.
THE WITNESS: I -- I haven't formed any opinions on that. I'm certainly not going to offer any in trial.
VIDEOGRAPHER: Be a good time to stop, Counselor?
MR. MONSOUR: Yeah, let's take a break.
VIDEOGRAPHER: This is the end of Tape Number 1 in the deposition of Roger McLendon, M.D. The time is 3:22 p.m. We are off the record.
(A recess transpired from 3:22 p.m. until 3:34 p.m.)
VIDEOGRAPHER: We are back on the record. The time is 3:34 p.m. This is the beginning of Videotape Number 2 in the deposition of Roger McLendon, M.D. Please continue.

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BY MR. MONSOUR:
Q. Dr. McLendon, we're back from a short break. Are you ready to continue?
A. Yes, sir.
Q. I have a question for you. On nerves, you said before that basically only nerve receptors can pick up pain and send it back up to nerves to the brain, right?
A. That's correct.
Q. What happens when a nerve is cut?
A. You generate an electric -- an action potential and you feel this sharp electrical surge and then it's numb.
Q. So -- so if a -- if during the process of surgery, implanting one of these TVT, if nerves are cut, there would be sharp pain during the surgery, but then afterwards, there would just be numbness?
MR. VOUDOURIS: Objection. Form and foundation. Go ahead.
THE WITNESS: As I said earlier, the acute pain is related to pain fibers locally regardless of the cause. Chronic pain is -- is what is differentiating what we don't know from the acute pain which we do know.

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BY MR. MONSOUR:
Q. Okay. All right. So back to my question. With the nerves that are cut, you said there's an electric signal that -- that transmits pain back to the brain?
A. It transmits this electrical-type signal. What happens is -- it's a very -- it's not like your standard copper wire that transmits a signal from the wall socket to your radio. What it amounts to is a very complex electrical signal that is -- that is based on sodium and potassium differences. And, I mean, I realize that's complicated, but it's not easy.
And when you cut it, you -- you release that differential of sodium and potassium across the cell membranes, and it causes a -- a -- just a sudden surge of an action potential or signal down that nerve. So the action potentials are -- is based in chemistry, not electricity.
Q. Okay, okay. However it -- the signal goes back up the nerve to the brain, and once it's cut, it -- there's an acute pain followed by numbness, correct?
A. Yes, sir.
Q. What -- what happens to a cut nerve? Does

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it die or does it -- what happens to it?
A. The end away from the nerve, the free end let's call it, degenerates. The -- not only does the fiber itself, which we call an axon, degenerate, but, also, the -- the insulation, which we call the Schwann cells, they also degenerate.
Proximally, back toward the spinal cord, there can be changes because your -- as you can imagine, keeping this chemical difference across the membrane takes a lot of energy. It takes -- it's a very active process. And that -- and when it's cut, it -- it winds up affecting the nerve all the way back up to its cell body. And the cell body of this nerve is found adjacent to the spinal cord. And -- and that nerve body will swell up.
Q. Okay. So once it swells up, what happens?
A. Then it begins to heal and the healing process results in sprouts back at the cut's stump of the -- of the nerve. And so you can -- sprout.
Q. So do -- do those sprouts then start to form nerve receptors?
A. They don't form nerve receptors. What they do is they start sprouting and trying to find the old canals of the old insulation which then as a -- as they migrate down the canals or the tubes, I

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should call them -- as they migrate down the tube, they go find their target organ or they find their -- their target site of what we call innervation.
Q. Okay. So what happens once it gets to the target site of innervation?
A. Then it will form either what we call a synapse or a receptor.
Q. Okay. So basically what you're telling me, I guess, is once a nerve is cut, the simplest way to put it is it kind of regenerates?
A. It doesn't kind of. It does regenerate.
Q. Okay. Great, great. So is that kind of like I had a client one time who was having -- who was having an epidural steroid injection in his neck, and the doctor actually hit his spinal cord with the needle, and it took a while for those -- that area of the nerve to regenerate. Does that sound right?
A. Not really, no, sir, because your spinal cord is part of your central nervous system, and the nerves are part of the peripheral nervous system. The peripheral nervous system can regenerate. The central nervous system can't.
Q. So what happens to someone that has that in their neck, in the central nervous system? Are they just stuck with it?

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A. They can develop numbness in that area, they can develop pain syndromes in that area, or the rest of the body can adapt.
Q. Okay. So in a surgery -- like let's say that we got a -- a TVT is implanted in a woman, and to implant the device, some nerves are cut. Do you follow me thus far?
A. I think I do, yes, sir.
Q. Okay. As those nerves are cut, they will attempt to regenerate or they will regenerate, correct?
A. Yes, sir.
Q. Will they regenerate through the TVT mesh?
A. They won't regenerate through the polypropylene. They will regenerate into the mesh if that's what you're asking. They will follow the scar tissue into the mesh.
Q. Okay. So these nerves -- these nerves, as they are growing or regenerating through the mesh, some might stop in the mesh and others might continue regenerating past the mesh, correct?
A. Well, it would be limited to where the scar tissue is and the smooth muscle. I mean . . .
Q. So if these nerves develop or grow into the mesh or into the scar tissue around the mesh,

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some of them will form new nerve receptors, correct?
A. Some of them can form new nerve receptors, that's right.
Q. Okay. Hypothetically, if over time the scar tissue around the mesh -- around those nerve receptors, if it contracts, could that cause pain?
MR. VOUDOURIS: Objection. Form, foundation.
THE WITNESS: It's -- it's unlikely that stretching on a nerve is going to cause pain. Stretching on a nerve usually just causes numbness, pressure on a nerve, like we talked about with carpal tunnel syndrome.
BY MR. MONSOUR:
Q. Okay. But I thought with regard to carpal tunnel syndrome, you were talking about how it was in an area that was being kind of pinched or squeezed away from the receptor, correct?
A. It doesn't matter. Anywhere along that nerve fiber, if there is pressure, if there is squeezing, then the nerve stops doing this complex chemical reaction that -- that is related to the action potential.
Q. Okay. But here's what I'm getting at. If a nerve regenerates into the scar tissue that forms

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around the mesh, some of those nerves might end up forming a receptor that's in that area, correct?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: I mean -- so you asked two ifs. And I mean, my -- my answer would be if, if, if, as well.
If it was a sensory fiber, if that sensory fiber were a pain fiber, if it was in an area that was irritated or there was an irritant, I should say a stimulus, one might -- could feel, I suppose, pain. And when I say I suppose, that leads into a hypothesis that can actually be studied. And the study of that would require looking at those nerve terminals against somebody who doesn't have pain.
And seeing -- and because, let me -- and this is an important point -- because you can say, my good- -- and this happens in science all the time. My goodness, I thought that would have been painful. But when you look over here at the other group, there is no pain, and they have the exact same distribution.
That's -- that's what we all the "aha moment" in science when we disprove the -- the hypothesis. But you've got to have the control

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data to do it. I can -- I can assume things.
But you've got to do the scientific study.
BY MR. MONSOUR:
Q. Okay. So let me ask a couple things and see if they are scientifically true and established. Is it true that peripheral nerves will regenerate?
A. That's a true statement.
Q. Is it true that peripheral nerves will regenerate and create new nerve receptors?
A. They can be associated with new nerve receptors, that's correct.
Q. Is it true that peripheral nerves that regenerate and create new nerve receptors are able to transmit pain?
A. That's what we don't know. You're asking me if it's true and established in science. It's not established in science.
Q. Okay. So are you -- are you saying -- and this is one where I'm not so sure I understand what you're saying so I'm going to ask the question.
You know that the nerves regenerate and you know that they create -- create new nerve receptors when they regenerate. Are you saying you're just not sure whether or not the newly created nerve receptors actually work?

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MR. VOUDOURIS: Objection. Form.
THE WITNESS: You asked me if I'm sure. And I'm doing my surety based on the evidence at hand. And the evidence at hand is insufficient. That's a great hypothesis. Perhaps the nerve receptors don't work.
Another hypothesis is that the nerve itself is not transmitting fibers. It's an ineffective -- is not transmitting pain fibers. That's a -- that's another hypothesis. All of these things need to be tested.
BY MR. MONSOUR:
Q. Okay. So -- so what you're telling me is the science -- you know that peripheral nerves regenerate. And you know that they will regenerate a new nerve receptor. And that's established by science, correct?
A. That's correct.
Q. But what you're saying is it has not been scientifically established that those nerve -- those newly regenerated nerve receptors actually work? Is that what you're telling me?
A. I'm saying that it's -- it's a number -- it comes down to number and distribution of nerves. Do you -- one nerve fiber, it might feel like an

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itch. Even though it's a pain fiber going off, it might feel like an itch. Multiple pain fibers may feel -- feel even worse. And then it's -- it all comes down to the science of number and density and distribution of nerve fibers before you can answer a question about -- related to pain.
Q. Okay. You lost me again. I was doing so good, Doc.
So here's my question again. Are you saying that the newly regenerated nerve receptors might not work or are you saying it depends upon how many of them have been regenerated?
A. Yes and yes.
Q. Okay.
A. Because if we knew the answer to your question, I go back to what we said last hour, that would help us come up with a plan on solving the problem of chronic post-surgical pain.
Q. How many nerves does it take for someone to feel pain?
A. To my knowledge, that is not known.
Q. It's not known?
A. To my knowledge, it is not known. And the way one does those studies is compare the -- the pain -- I'm sorry, the sensation of pain, the

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biopsies from patients who are suffering pain versus biopsies of patients who have no pain. You look at the nerve terminals. You count the distributions. You do the study. And go, oh, my goodness. Now, that's the -- that's making a big assumption that is not founded in science.
We have a -- you have a problem of chronic post-surgical pain and they're looking at it from multiple locations. Is it related back to the brain? Is it related to the spinal cord? The question you ask is a good question. But it has to -- is a good test, I should say. But it has to be done in science where you compare the nerve terminals versus in a painful person versus a nonpainful. If you don't have those answers, you can't make that conclusion.
You can say, oh, look at all the nerve terminals. Once again, you go, I'm sorry, this is one of the patients that doesn't have pain. And you go, well, I just don't know why. And that's -- that's how one does science.
Q. Okay. Let's -- let's go back to -- let's go back to talking about nerve regeneration in the situation where a TVT sling has been implanted.
A. Yes, sir.
Q. In that situation where a nerve has been

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cut and the nerve regenerates and there's a nerve receptor that is regenerated in the scar tissue area of the TVT sling, you follow me thus far?
A. Well, you -- you're stating it as if we both agreed that that was a fact, and we actually started out as a hypothetical.
Q. Okay. Well, I'm just kind of setting up the -- the situation, okay? You agree that TVT slings are implanted, correct?
A. I agree that they are implanted, yes, sir.
Q. You agree that scar tissue forms around them, correct?
A. That's correct.
Q. You agree that during the process, some nerves are cut, correct?
A. I didn't agree to that. You said, let's assume that some nerves are cut.
Q. Okay. So you think -- is it -- would it be physically possible for someone to implant a TVT sling without cutting any nerves?
A. That would seem unreasonable.
Q. Okay. So let's focus on reason, Doctor.
A. Well, no, no, no. Let's -- I said that would seem unreasonable, but I haven't done the studies, and those studies are not done. That would

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seem -- but you have -- there's so much that -- that is scientifically need- -- that is begging to be studied.
Q. Well, there are certain things we know. And one of the things is you probably aren't going to be able to do a surgery without cutting some nerves somewhere, right?
A. It sounds reasonable.
Q. Okay. So let's stick with reason. In this situation and we've got a nerve that is cut during the TVT procedure, correct?
A. Correct.
Q. That nerve regenerates, which you know happens, correct?
A. Yes, I do.
Q. And that nerve then grows and regenerates a new nerve receptor in the scar tissue. Assume that for me, okay?
A. Okay.
Q. What would need to happen, assuming that nerve receptor works, to cause pain?
A. It would need to be stimulated.
Q. Okay. Is there a way that scar tissue can be stimulated or that scar tissue can move in a way that stimulates a nerve receptor?

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A. I'm not sure because -- I would imagine that it -- it would be true, but so many scars are numb. And so -- so many of the paresthesias around an area that's cut are not painful as they're just more -- they feel like electricity. I mean, I think we probably all have cut some part, and I've got one part on my finger that is a scar where I cut a nerve, and when I press on it, it feels like electricity, kind of like a small version of a funny bone.
Q. Okay.
A. But it's not painful. It just feels like electricity.
Q. Okay.
A. And in the -- in the area beyond it is numb.
Q. Let me ask this question, Doctor. If a nerve receptor is surrounded by scar tissue and the scar tissue contracts, can that cause pain?
A. As I said before, it's more likely than not to cause numbness. The contraction of a scar puts pressure on the -- on the nerve, and then as we have discussed many times before, that would probably cause numbness.
Q. Okay. But what if there was actual contraction not just of the nerve but of the nerve

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receptor itself?
A. That -- as I said, that -- it sounds reasonable to consider that would be numb.
Q. Okay. Could contraction around a nerve receptor cause pain, in your opinion?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: Could contraction -- is that -- is that the word you used?
BY MR. MONSOUR:
Q. Yes, sir. Could contraction of scar tissue -- assume with me that there is a nerve receptor that is embedded in scar tissue.
A. Yes, sir.
Q. Okay? If the scar tissue contracts, could that cause pain?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: Once again, I will say to a reasonable human being, that sounds like a reasonable hypothesis that needs to be tested. Because if that were true, that would result in a different approach to chronic post-surgical pain. It would give a testable hypothesis.
There are a lot of people working on chronic post-surgical pain, and they have yet to come up with an answer. They have done studies

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like this. They've -- they've done nerve blocks on these patients. They've done -- they've cut the nerves. And when they get initially hopeful results, they test it on bigger studies, and they've all failed. Nerve blocks, cut nerves, they've all failed. Now, not necessarily related to TVTs, but to other areas of pain, abdominal pain, whatever, hernia surgery, these direct approaches to numbing up the nerve, breaking the nerve, cutting the nerve, they've all failed.

That means there's -- there's driven reasonable pain scientists to come up with other hypotheses that just say, there's this 2 percent of people who have chronic pain -- post-operative pain syndromes, and we don't know why. Your hypothesis is reasonable. It needs to be tested.

BY MR. MONSOUR:

Q. Do you think my reasonable hypothesis should have been tested by Ethicon or looked at by Ethicon before they sold these products that result in scar formation around the mesh?

MR. VOUDOURIS: Objection. Form, foundation. Beyond the scope.

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THE WITNESS: I don't know what Ethicon did before they started implanting these TVTs.

BY MR. MONSOUR:

Q. Wasn't -- my question wasn't, did they. It was, should they have?

MR. VOUDOURIS: Objection. Beyond the scope.

THE WITNESS: I haven't been asked to form an opinion on that, and I certainly haven't gone out of my way to think up one.

BY MR. MONSOUR:

Q. Well, it's not one that really requires a lot of study. Should -- you mentioned several scientific studies that are reasonable hypothesis that I've mentioned before, and it would be reasonable to look at something. Shouldn't Ethicon, as the manufacturer of this product that's implanted to many, many women, shouldn't they have done the scientific study to determine if this reasonable hypothesis is right before they sold it to a bunch of women?

MR. VOUDOURIS: Objection. Beyond the scope.

THE WITNESS: I haven't formed an opinion on that, sir. And I'm not going to testify in

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trial about it.

BY MR. MONSOUR:

Q. Well, that doesn't mean we're not going to ask you a question about it at trial. It doesn't mean it's not fair game. And this is a discovery deposition. This isn't trial testimony. So I'm asking you a question and I'd like you to answer it.

MR. VOUDOURIS: Objection. Asked and answered twice. Beyond the scope.

MR. MONSOUR: I want an answer to the question. He's being evasive.

BY MR. MONSOUR:

Q. Please answer it, Doctor.

MR. VOUDOURIS: He is not being evasive. Calm down. He answered your question twice.

BY MR. MONSOUR:

Q. Answer the question.

A. I haven't formed an opinion on this, and I'm not going to offer testimony at trial.

Q. Should they have done the study before they sold this product, Doctor? Answer the question.

MR. VOUDOURIS: Objection. Asked and answered three times now.

THE WITNESS: I haven't formed an opinion on that, and I'm not going to offer one at

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trial. I do not develop prostheses or do any phase 1, 2 or 3 studies on implantation of prostheses. I never have done. I don't know the science. I don't know the medicine. I'm not going to offer an opinion on that.

BY MR. MONSOUR:

Q. And maybe for those reasons, you're not a good expert for this case, don't you agree?

MR. VOUDOURIS: Objection.

THE WITNESS: Well, I think I'm a pretty good neuropathologist.

BY MR. MONSOUR:

Q. But you don't know anything about how mesh operates in the body, true?

MR. VOUDOURIS: Objection.

THE WITNESS: I know that the mesh is used to put a -- a kink in the ureter and -- and help women with stress incontinence.

BY MR. MONSOUR:

Q. But you don't know how this mesh responds in the body and how nerves respond within that mesh, do you?

MR. VOUDOURIS: Objection.

THE WITNESS: I -- I know as much as science allows me to know, and it's more than

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Dr. Iakovlev has -- has put forth as a -- as a reasonable hypothesis.
BY MR. MONSOUR:
Q. How many studies has Dr. Iakovlev done looking at explanted mesh samples?
A. How many scientific studies? None.
Q. How many studies of any type has he done?
A. Scientific studies? I have no idea.
Q. How many -- how many published studies has he done?
A. I have no idea on -- on -- I think he's had five or six observational studies reported in -- in scientific journals.
Q. And those are peer-reviewed scientific journals, aren't they?
A. And they are observational studies that generated hypothesis that tested no hypothesis.
Q. Great. What was my question?
A. The scientific method -- the scientific method involves taking a hypothesis, comparing -- doing the studies comparing --
Q. Did I ask you -- I said, were they peer-reviewed journals? What is the answer to my question?
A. I think all but one was a peer-reviewed

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journal.
Q. How many peer-reviewed -- how many articles have you gotten published in peer-reviewed journals concerning explanted mesh?
A. None.
Q. Who's in a better position to opine as to how the body responds to mesh implants, you or Dr. Iakovlev?
A. A board-certified neuropathologist is in a much better position to discuss the mechanisms of pain in this particular situation.
Q. You are a board-certified neuropathologist who has never looked at a TVT explant in your life, correct?
A. I --
MR. VOUDOURIS: Objection.
THE WITNESS: I have not until today.
BY MR. MONSOUR:
Q. Don't you think you would need to look at a TVT explant in order to render opinions, Doctor?
MR. VOUDOURIS: Objection. Asked and answered.
THE WITNESS: I have looked at these explants, I've looked at Dr. Iakovlev's evidence, and he does not look at things that

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could even be remotely considered to be pain fibers.
BY MR. MONSOUR:
Q. Actually, they could be pain fibers. They just haven't had the right stains put on them, correct?
A. That would be called science.
Q. No, listen to my question. Listen to my question. What you're saying is Dr. Iakovlev's slides don't have the right stains on them; however, if Dr. Iakovlev had put -- put certain different stains on his slides, they very well might show nerve receptors in the area, correct?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: He has half the appropriate tissues to do that study. As we have said numerous times, he needs to have control studies of vaginal tissue of patients with TVT meshes that have not -- do not experience chronic pain. And then he needs to be able to do the appropriate stains to find the non-myelinated fibers and do a density study which it would just test one hypothesis of the entire chronic pain syndrome problem.

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BY MR. MONSOUR:
Q. But let's talk about that. What you're saying is we need a control group of women who have an implant that is appropriately working and not causing pain, correct?
A. I didn't say "appropriately working." Dr. Hill found some women who had stress incontinence, or voiding dysfunction is what he called them, and compared those removed meshes with those of women with chronic pain.
Q. Okay. Do you believe the Hill study is authoritative?
A. I don't believe any study's authoritative, but it was a pretty good study done on 130 women, 70 who had one set of symptoms and 60 who had another.
Q. Okay. Hold on. You've cited the Hill study, but you do not believe it is authoritative, correct?
A. I've cited the Hill study as a good study. Authoritative studies take -- or fluctuate in -- in -- as our knowledge base increases.
Q. Do you think the Hill study is a reliable study?
A. I believe it was a very good, reliable

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study.
Q. Do you believe the Vervest study is a good, reliable study?
A. I'm not -- I -- I realize I quoted it. I don't remember the study. May I look it up?
Q. Sure. And just so you know, Doctor, I'm going to ask you about all the studies that you've got in your report. So you might want to look at each of them. And I'm going to ask you each the same question. Is each one of them a good, reliable study? You might as well look at them now.
A. (Reviewing documents.) I can't find that Vervest study.
Q. Are you getting close?
A. I've looked through everything, but I can't find the Vervest study on -- on transections of nerve and TVTs.
Q. Okay. Well, let's go through them one by one.
A. All right.
Q. We'll start with Vervest even though you don't have it. Or actually let's -- let's start with -- yeah, let's start with Vervest even though you don't have it.
A. All right.

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Q. Even though you don't have it in front of you, from what you remember, was Vervest a good and reliable study?
A. I thought it had useful evidence in it, yes, sir.
Q. Okay.
A. I'm trying -- let me find my -- there it is, right on top (indicating). At least I can find my reference list. Okay.
Q. Okay.
A. All right.
Q. Okay. So Vervest, good and reliable?
A. It was a useful study with a useful piece of data.
Q. Okay. Svenningsen, was that a good and reliable study?
A. Risk Factors for Long-Term Failure of the Retropubic Tension-Free Vaginal Tape Procedure, I remember it. It gave some data looking for independent risk factors. Yes, sir, it was useful.
Q. Okay. Was it good and reliable?
A. I mean, I feel like the Pope saying something is good and reliable, sir. So I mean, it was useful scientific study that I read through, and it seemed reasonable.

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Q. Okay. The Elmer study, was that a good and reliable study?
A. Histologic Inflammatory Response to Transvaginal Polypropylene Mesh for Pelvic Reconstruction, I did read it, and I did quote it in my paper, in my report. I thought it was useful.
Q. Okay. The Benadavid report, was that good and reliable?
A. The mesh-related syndrome, I read it. It gave some useful numbers. So it was a -- it was an observational study that I was able to find some useful data.
Q. Okay. The Elmer study, was that a good and reliable study?
A. I mean, I -- I'm not agreeing to any of these "goods," but I have the Elmer study right here. Hold on. I had it in my hand.
Q. The title is "Histological Inflammatory Response to Transvaginal Polypropylene Mesh for Pelvic Reconstructive Surgery" --
A. Oh, it's right here (indicating), yeah.
Q. Got it?
A. I've got it in my hand. I just -- that was a -- that was a useful study, yes, sir.
Q. And then you got the Smith study. Was

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that a good and reliable study for you?
A. That was a -- it had useful information that I -- I considered --
Q. Okay.
A. -- in -- in writing up my report.
Q. And then the Smith study, was that a useful, helpful, reliable study?
MR. VOUDOURIS: Objection.
THE WITNESS: I think you just asked about that, sir.
BY MR. MONSOUR:
Q. Oh, okay. Did I say Smith or Hill?
A. Smith. You said Smith twice, sir.
Q. Okay. So Smith you've answered. Hill, did you find that to be a good, useful study?
A. I found it a useful study to provide interesting data.
Q. Okay. Can you pull out the Hill study real quick?
A. Yes, sir (Witness complies).
Q. If you look under the conclusions on page 1, it says, "Vaginal Tissue Fibrosis." Do you see that?
A. Yes, sir.
Q. What is vaginal tissue fibrosis?

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A. Scar.
Q. Say that again?
A. Scar.
Q. Okay. In the Hill study, 90.8 percent of the excised specimens showed some inflammation, correct?
A. That's my understanding, yes, sir. 9.2 percent showed no inflammation.
Q. And can inflammation cause pain?
A. That's an interesting question. Acutely, acute inflammation can -- can cause intense pain, but inflammation of a nerve quite often causes numbness because you wind up not only affecting the nerve, Schwann cells, but also the nerve fibers. So typically, most inflammatory nerve diseases cause numbness.
Q. Do some inflammatory processes cause pain?
A. Yes, abscesses do.
Q. Any others?
A. Well, acute inflammation can cause pain.
Q. Okay. Can chronic inflammation cause pain? Can it?
A. Can it? I suppose it can.
Q. Okay.
A. That -- that was a useful hypothesis that

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was studied by the -- the Hill study, in fact. Dr. Hill thought it could. Proved it couldn't. But he thought it could.
Q. What prompted you to get involved in the transvaginal mesh litigation?
A. One of the pathologists here asked me my opinion about a nerve -- a photograph and asked me if that was painful.
Q. And who was that pathologist?
A. Dr. Stanley Robboy.
Q. How do you spell that last name?
A. R-O-B-B-O-Y.
Q. And then did he put you in touch with Ethicon?
A. No, sir. The next thing I know, I'm -- I'm -- I was contacted by I believe it was Mr. Voudouris.
Q. Okay. And does Dr. Robboy, does he have a relationship with Johnson & Johnson?
A. Oh, I have no idea. He's one of our retired pathologists who still is active on the university side.
Q. If you look at the -- well, you don't have the Vervest study, correct?
MR. VOUDOURIS: Doug, actually, I just

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pulled it up on a -- on a cell phone, if you want me to hand it to the Doctor.
MR. MONSOUR: That might be hard to read or the court reporter probably has it on her iPad that we sent over to her. It might be easier to read it on that.
MR. VOUDOURIS: That's fine. You want to take a -- just go off the record for 30 seconds for her to look?
MR. MONSOUR: Yeah, absolutely.
VIDEOGRAPHER: Time is 4:23 p.m. We are off the record.
(A recess transpired from 4:23 p.m. to 4:24 p.m.)
VIDEOGRAPHER: We are back on the record. The time is 4:24 p.m.
BY MR. MONSOUR:
Q. Okay. Doctor, I guess on the iPad in front of you, you have the Vervest study, correct?
A. Yes, sir.
Q. And it's actually a case report of a single incident that happened, right?
A. Yes, sir.
Q. So even though it's not -- there's no controls or anything like that, it's a case report

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that you picked out because you thought it could be helpful, right?
A. Well, the title certainly was interesting.
Q. Okay. But you thought it was helpful, right?
A. That's correct. The -- the discussion was useful and the results, that's correct.
Q. And just so I can understand this, your report here is -- it looks like the text of your report is one, two, three -- like five pages? Five pages, right?
A. I suppose so, yes, sir.
Q. And you wrote your report, right?
A. Yes, sir, of course.
Q. And did you write all of it?
A. Yes, sir.
Q. And how did you select which articles you wanted to put in your report?
A. I received a memory stick from a Mr. Voudouris, and then I also went online and looked up some papers on my own, I believe. And I also needed to reference some data -- I also looked at some data that was in some standard textbooks of neurology and -- and epidemiology.
Q. Okay. What type of data on neurology and

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epidemiology were you needing to look at?
A. I looked at --
MR. VOUDOURIS: Objection. Go ahead.
THE WITNESS: -- I looked up the Kandel and Schwartz book and -- in order to reference a standard text regarding pain fibers. And I also looked up the Midroni book coauthored by Dr. Juan Bilbao to see how -- to see a standard reference for anybody to look at about how to process nerve. Also discussed Renaut bodies, if somebody wanted to look up, that was a useful reference. And the epidemiology was -- study was -- the Ma book -- I mean, the Ma chapter was just talking about different scientific studies.
BY MR. MONSOUR:
Q. The -- the studies that are listed in your report on page 2, the Vervest, Svenningsen, Benadavid, Elmer, Smith and Hill, did -- did you come up with those studies, or did those come from Mr. Voudouris' memory stick?
A. Oh, I don't remember exactly, sir.
Q. Did any of them come from your own independent research?
A. Well, it -- that was fairly easy to do because you just read the -- the papers and then go

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into the bibliography and find an interesting article and -- and look it up on PubMed. Nowadays looking up papers is a -- is a process of about two minutes.
Q. Okay. You did your searches on PubMed?
A. Yes, sir.
Q. Okay. If we look at the Vervest article, it says -- let me see -- it's talking about -- if you look on the last page of the article?
A. Oh, here it is. Okay.
Q. In the second to the last paragraph?
MR. VOUDOURIS: Hold on. He has to get there.
THE WITNESS: Second-to-last paragraph. Okay. I'm on page 667.
BY MR. MONSOUR:
Q. Okay. And in the last part of it, it says, "However, if no neurological damage or loss of neural innervation was found after surgery, it is likely that only small branches of this nerve were involved."
Do you see that?
A. I do.
Q. And then it continues, "Due to the fact that probably only small branches were involved and due to anatomical variations in the course of these

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nerves, it is doubtful that this type of complication can be avoided, i.e., by more lateral positioning of the TVT needle."
Do you see that?
A. I do.
Q. And it says, "It is doubtful that this type of complication can be avoided."
What type of complication is that?
A. I believe he's referring to nerve section.
Q. Referring to what?
A. Nerve section.
Q. And is nerve section another way of saying cutting of nerves?
A. Yes, sir.
Q. What is a neuroma?
A. A neuroma, if -- can I just jump to traumatic neuroma?
Q. Sure.
A. A traumatic neuroma occurs when the nerve is attempting to regenerate, cannot find the distal end that it -- it was severed from.
Q. Hello?
A. Hello. I'm here. Can you hear me?
Q. Something just happened.
MR. VOUDOURIS: We can hear you.

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BY MR. MONSOUR:
Q. Okay. Now it's working.
A. All right. I'm sorry. I probably twisted the receptor here.
Q. Let's -- let's start that again. Let's start that again because I'm not for sure what you heard and what I heard. So let me ask you again, what is a neuroma?
A. A traumatic neuroma is when a nerve is sectioned and, when in the process of sprouting and regenerating, attempts to find the distal canal that would take it back to its target organ, but instead of finding its targeted organ -- I mean, the canal, what it does is just grow in a circle. And you've got multiple nerves growing in a circle.
Q. And what happens when a neuroma or a traumatic neuroma forms?
A. Patients complain of itching. Some complain of pain, electrical-type pain. It forms a mass that is stimulated by pressure.
Q. And basically what happened in this -- in this case was, as a result of or following the surgery, some traumatic neuromas formed, correct?
A. I don't --
MR. VOUDOURIS: Objection. In this case,

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what do you mean by that, Doug? I'm sorry. Are you referring to the article?
BY MR. MONSOUR:
Q. Yeah, I mean in the -- in the Vervest article. And I said "in this case" because the Vervest article is simply a case report. It was only one case. Hello?
A. Hello. I was refamiliarizing myself with the article.
Q. Okay.
A. It appears that they -- they put tape through nervous tissue.
Q. Okay. Can that cause pain?
A. I don't know. It can -- it -- acutely, it seemed reasonable it could cause pain. Chronic pain syndrome, I don't know. In this particular case, she complained of persistent pain.
Q. Okay. If you look at the end of the document in the last paragraph, it says, "Especially when application of a local anesthetic alleviates the pain, the possibility of an entrapment or damage to a nerve should be considered."
Do you see that?
A. I do.
Q. What does it mean when they're saying "an

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entrapment"?
MR. VOUDOURIS: Objection. Form.
BY MR. MONSOUR:
Q. Is that the neuroma?
A. I don't know. I don't think it is. It sounds like the nerve is entrapped in the tape some way or another.
Q. At the end, it says, "Post-TVT neuralgia due to nerve entrapment or damage by the tape needs to be added to the increasing list of potential complications of this procedure."
Do you see that?
A. I see that.
Q. What is "neuralgia due to nerve entrapment"?
A. It is a abnormal sensation related to location. In other words, it's -- it's a feeling that one gets that is foreign to that location. So neuralgia can be a persistent sensation, let's call it.
Q. Would neuralgia in this situation, would it be persistent pain?
A. I believe she describes persistent pain so I would accept that patient's characterization.
Q. And then it says -- it says, "This needs

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to be added to the increasing list of potential complications of this procedure."
Do you see that?
A. I see that.
Q. Do you agree with that statement?
A. I -- I agree that that is a hypothesis that needs to be tested. That's correct.
Q. Do you agree that it is something that the doctors should be warned about?
MR. VOUDOURIS: Objection. Beyond the scope.
THE WITNESS: I have -- I have not formed an opinion. And I'm not going to be offering testimony to that in trial.
BY MR. MONSOUR:
Q. Do you understand why I'm asking the question, though? I mean, I'm simply reading the article that I got from you, Doctor, and it says that. That's why I'm asking the question.
A. I see. And I noted that this was a rare complication and I -- and that was my comment. My -- my comment, as I put it in my report, was "Statements related to pain pathogenesis fail to explain as the pain is related to the mesh or to an unnoted complication of the operative procedure." And this

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was an unnoted -- this was a complication of the operative procedure, what Vervest described.
Q. Okay. If you will pull out the Elmer article, I would like to ask you a question about the first paragraph.
A. (Witness complies.) Yes, sir.
Q. It says -- at the end of the first paragraph, it says, "The unique vaginal micro environment dynamics biochemical exchange and immunological response prevent the inference of results from other areas of biomaterial use such as inguinal hernia surgery to the pelvic floor."
Do you see that?
A. Yes, sir.
Q. Do you agree with that statement?
MR. VOUDOURIS: Objection.
THE WITNESS: I have no reason to argue against it.
BY MR. MONSOUR:
Q. Okay. If you go back to the Hill article and turn to the last page of it?
A. Yes, sir.
Q. Now, it says on the last paragraph, it says, "Giant cell reaction also appears to be a ubiquitous finding in excised vaginal mesh. And the

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vaginal tissue response to mid-urethral mesh is histologically similar for fibrosis and giant cell reaction in all patients."

Do you see that?

A. Yes, sir.

Q. Is that a chronic condition?

A. Yes, sir.

Q. And then I would like to ask you, of -- of these studies that you have quoted in your paper or in your report, are they all observational?

A. No, sir.

Q. Is -- which one is not observational?

A. The Hill study in particular is very useful because it compares a known control with a known abnormal group.

Q. It was not a randomized control trial, correct?

A. It was not. It said it was -- the paper itself says it was limited by its retrospective nature.

Q. Okay. Are the other studies that you mentioned, are any of them observational?

A. I'm quite sure a lot of them were, sir. I mean, I can't pull them out right now. There are several articles that I pulled out right now.

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Q. Okay. Can -- can you learn some good information from observational studies?

MR. VOUDOURIS: Objection. Form.

THE WITNESS: You can learn some good information from a observational study. It's very much like a travel pamphlet describing where things are and where to find things. It's -- you can find useful information. It's not scientific. It's more artistic, but it's -- you can find information.

BY MR. MONSOUR:

Q. Okay. Have you ever looked at what the rate of chronic pain is in patients that have been implanted with TVT slings?

A. I noticed in the Nature Reviews paper by Dr. Blaivas, that it was about 2 percent.

Q. Are pain receptors the only -- are pain receptors the only ones that can signal pain, or can others do it as well?

A. The A delta and C fibers are your pain fibers.

Q. And those are the only ones?

A. Those are the ones that are -- have been scientifically proven to mediate pain.

Q. Okay. Is there anything that can change

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the sensitivity of a nerve receptor?

MR. VOUDOURIS: Objection.

THE WITNESS: It's my understanding that there's not. At least on a -- on the periphery, that's true.

BY MR. MONSOUR:

Q. Could you repeat that? You kind of cut out for a second.

A. Oh, I'm -- I said there's nothing that increase the sensitivity of a peripheral nerve receptor.

Q. Okay. Does chronic inflammation have any effect on a nerve receptor?

MR. VOUDOURIS: Objection. Form.

THE WITNESS: That's a study that was addressed in the vaginal mucosa, the vaginal micro environment and was said not to, by the Hill study.

BY MR. MONSOUR:

Q. In your practice when you receive specimens, do you look for pathological features to explain the symptoms?

A. In a limited scenario, you can do that, yes, sir.

Q. If you were attempting to determine -- if

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you were attempting to determine if an excised sling that was reported to be causing pain, if it was actually the source of the pain, what would you specifically look for?

A. In this particular case, since the cause of pain is unknown, you would be looking for abnormal nerve density, location, fibers like that and compare it to normal, as that would be a localized testing of a hypothesis. The problem is that's not always -- and surprise me -- that's not always the cause of pain in these women because they can have more central causes of pain related that they truly believe is related to that area of surgery.

Q. If you receive a specimen from a surgeon and it says "painful lesion," and you see a foreign body type of reaction and some foreign particles, would you make a diagnosis that the foreign body was causing the pain?

MR. VOUDOURIS: Objection.

THE WITNESS: I would not. I would just diagnose it as vaginal mucosa with scar, foreign body giant -- and foreign body giant cell reaction and anything else I noticed.

BY MR. MONSOUR:

Q. Is it a fair statement that in writing

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your report, you wouldn't put that the sling either caused or did not cause the pain; is that true?
A. Well, it wouldn't be taken seriously by the surgeons or the OB/GYNs.
Q. So you wouldn't write it in there either way?
A. That's correct.
Q. Tissue needs to be innervative or innervated to have pain, correct?
A. Yes, sir.
Q. If there are no nerves in tissue, it's not going to feel pain, right?
A. That's correct.
Q. When you look at the slides that you see from Dr. Iakovlev, do you agree that they show inflammation?
A. There was very modest lymphocytic infiltrates. Whether that's related normal to the vaginal mucosa or whether that's inflammation, it's -- it's not clear. The vaginal mucosa is exposed to the environment and has its own immune system.
Q. Which area has a higher level of innervation, the vagina or the anterior abdominal wall?

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A. The -- the level of innervation of the vagina is quite minimal because of the stretching it has to go through in -- in childbirth. If it had a large number of pain fibers, the -- the pain of childbirth would be unbearable. But as far as the number of abdominal nerves versus vaginal nerves, I don't know.
MR. MONSOUR: Okay. Why don't we take a break. Let me go through some of my notes and see some other things. I might be able to kind of cut some of this short. So let's take a 15-minute break and regroup. Does that sound okay?
VIDEOGRAPHER: We only have about seven minutes remaining so I'll end this tape.
MR. MONSOUR: Yeah, go ahead and end the tape.
VIDEOGRAPHER: This is the end of Videotape Number 2 in the deposition of Roger McLendon, M.D. The time is 4:49 p.m. We are off the record.
(A recess transpired from 4:49 p.m. until 5:05 p.m.)
VIDEOGRAPHER: We are back on the record. The time is 5:05 p.m. This is the beginning of

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Tape Number 3 in the deposition of Roger McLendon, M.D.
Please continue.
COURT REPORTER: We have the hard copy exhibits now, Mr. Monsour.
MR. MONSOUR: Okay, great. Thank you.
BY MR. MONSOUR:
Q. Dr. McLendon, we had a short break. Are you ready to proceed?
A. Yes, sir.
Q. Okay. You have read the entirety of Dr. Iakovlev's report, correct?
A. Yes, sir.
Q. With regard to pain generation by the TVT, is it possible that Dr. Iakovlev is right?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: It -- is it po- -- is it possible is not a very scientific question. I mean, is it --
BY MR. MONSOUR:
Q. That's why the lawyer asking it.
A. Yes, sir.
MR. VOUDOURIS: That's why I objected to form.
THE WITNESS: I appreciate that. It's --

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it's not possible using the stains that he has used in this particular instance.
BY MR. MONSOUR:
Q. Is it not even -- not looking at the stain, but just the theory of what is causing what, is it possible that Dr. Iakovlev is correct?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: I mean, it's -- we have a saying where I grew up about a blind hog finding an ear of corn. Is it possible that he can -- that he has -- he has completely ignored a large part of the pain literature concerning causes of chronic pain -- chronic post-surgical pain syndromes. I don't know how to answer, is it possible when he has shown no evidence that he knows what he's looking for.
BY MR. MONSOUR:
Q. Okay. I'll ask my question again, though. Is it possible that Dr. Iakovlev is correct?
MR. VOUDOURIS: Objection. Asked and answered.
MR. MONSOUR: I think it's a simple question and it's just a simple answer.
MR. VOUDOURIS: Objection.
THE WITNESS: It -- it's unlikely that he

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knows what he's talking about.
BY MR. MONSOUR:
Q. Okay. Let me ask my question again for a fourth time. Is it possible that Dr. Iakovlev is correct? Yes or no?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: Let me try a different way. He's -- he's generated an interesting hypothesis that needs testing that he has yet to test. As far as base -- the scientific basis for his understanding, it's impossible that he has found the answer to this problem.
BY MR. MONSOUR:
Q. Is it possible that Dr. Iakovlev is correct?
MR. VOUDOURIS: Objection. Asked and answered.
BY MR. MONSOUR:
Q. Yes or no?
A. It is impossible for him to make the conclusions he has made based on his evidence.
Q. You're -- you're talking about proving it. I'm just asking you, is it possible that he is right and he just needs to do more to establish it?
MR. VOUDOURIS: Objection. Form. Asked

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and answered.
THE WITNESS: I think he's looking up the wrong tree.
BY MR. MONSOUR:
Q. And I'm going to go back to my question. Is it possible he is correct?
MR. VOUDOURIS: Objection. Form. Asked and answered.
THE WITNESS: All right. So -- all right. Let me -- let me just take it through. The science says that it is not possible that scarring, vaginal tissue correlates with pain. That's the Hill study. The Hill study also indicates that it's not possible that chronic inflammation is associated with pain.
So now we're left with these pain fibers that aren't generating any pain so -- in relation to his other two hypotheses. I mean, he's generated hypotheses that are being disproven as fast as he can generate them. I think it is more likely than not that he is not -- it is not going to find the answer he is hypothesizing.
BY MR. MONSOUR:
Q. Okay. And that's primarily based upon the

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Hill study, correct?
MR. VOUDOURIS: Objection.
THE WITNESS: The Hill study is a very good paper, but there are other papers that also talk about the drop in inflammatory cells in the vaginal mucosa after the implantation of these meshes so -- they do pre-op and post-op vaginal biopsies. They implant the -- they do pre-op biopsies. They implant the mucosa -- the TVT, and then they do a post-op and find that inflammation actually decreases. Everything he -- he hypothesizes is proven wrong.
BY MR. MONSOUR:
Q. You stated earlier when we started talking on the subject, that Dr. Iakovlev has ignored some of the science. Can you specifically tell me what Dr. Iakovlev has ignored, and I'll take it at least one of the things you believe he has ignored is the Hill paper, correct?
A. That's correct. The --
Q. What else has he ignored?
A. The other things is the non-local injury theories related to chronic persistent post-surgical pain that is unrelated to local site damage that is a central nervous system, more dorsal root ganglion,

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the other things we've talked about.
Q. Where would I find that literature so I can go read it?
A. It would be on chronic persistent pain.
Q. Look for chronic persistent pain?
A. I believe so.
Q. And who is the most knowledgeable author on chronic persistent pain? What's -- who's the best person that I should consult with on that?
MR. VOUDOURIS: Objection. Form, compound.
THE WITNESS: Number one, this is not my area of expertise. Number two, the most common author has a foreign name that I can't spell, much less pronounce. I'll be glad to provide --
BY MR. MONSOUR:
Q. Chronic persistent pain?
A. Chronic post-surgical pain, chronic persistent pain. This -- this is an area that -- that was a -- a single sentence in my -- in my report that said that there are patients who have unknown causes of chronic persistent post-surgical pain, and other reasons for post-surgical pain. And we've spent a large part -- a large part of this deposition on a single phrase in my dep- -- in my report.

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Q. Does that bother you?
A. Not at all, sir. But it's not something that I have my expertise in. My expertise is in neuropathology and neuroanatomy.
Q. Okay. Is there a certain textbook I should get for chronic persistent pain?
A. I'm not sure. I'm not aware of one.
Q. Okay. But what you're saying is that you -- that Dr. Iakovlev has ignored the chronic persistent pain literature and you don't know what I should go look at to go -- to go look at that subject, right?
A. That -- that's correct.
Q. And is it a fair statement to say that with regard to post-surgical chronic pain, you do not know how that is caused?
MR. VOUDOURIS: Objection.
THE WITNESS: That is a -- as I have said several times, that is an area of active research because drug companies would dearly love to be able to help patients who have chronic persistent pain, chronic post-surgical pain.
BY MR. MONSOUR:
Q. If I asked you a question -- if I asked

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you, if I said, what is the cause of chronic pain following surgery, your answer to me would be "I don't know," correct?
A. That's correct. There are a number of hypotheses.
Q. One of the people that is actually attempting to investigate pain following the implantation of transvaginal mesh is Dr. Iakovlev, correct?
MR. VOUDOURIS: Objection.
THE WITNESS: Dr. Iakovlev is collecting cases and examining them and making observational reports based on what he's found, generating hypotheses with no experimental evidence to prove or disprove, no plans for experimental evidence that I can tell that he has reported about what needs to be done next.
BY MR. MONSOUR:
Q. Right. But he's actually looking into this issue, unlike you, correct?
MR. VOUDOURIS: Objection.
THE WITNESS: He seems to be actively collecting cases and looking at -- at, and doing observational studies on these vaginal biopsies.

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BY MR. MONSOUR:
Q. What have you done to determine the cause of pain or chronic pain in women with transvaginal or TVT implants?
A. What have I done actively? I have no active research program in this area.
Q. Do you plan to do one?
A. I do not. Excuse me. I do not at this time.
Q. Other than the Hill article and the topic or research involving the topic of chronic persistent pain, has Dr. Iakovlev missed anything else?
MR. VOUDOURIS: Objection. Broad.
THE WITNESS: Repeat the question?
BY MR. MONSOUR:
Q. Other than the Hill -- you said earlier that Dr. Iakovlev had ignored some science, right?
A. Yes, sir.
Q. And one of the things you said he ignored was the Hill article, correct?
A. That's correct.
Q. And one of the things that you also said he ignored was literature involving chronic persistent pain, correct?
A. That's correct.

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Q. Is there anything else that he's ignored that -- that you can identify?
A. Well, I'm not aware that he has quoted the Elmer paper that we discussed about the drop in inflammatory cell infiltrates in the vagina pre- and post-biopsy. I'm not at all aware that he's looked at any other studies. But there are not that many active studies right now on this -- on chronic persistent pain in these TVT patients.
Q. Do you believe you've ignored any of the published finds that would be pertinent?
MR. VOUDOURIS: Objection.
THE WITNESS: Have I ignored it? No.
BY MR. MONSOUR:
Q. Do you believe that the Hill article has any limitations?
A. It's a -- it states that it's got -- it is limited by its retrospective nature.
Q. Is there anything else that it's limited by?
A. They didn't look for nerve endings. That would have been useful, wouldn't it?
Q. In the Hill article, when were the samples collected with regard to the timing from the date of surgery?

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A. If they were pathology studies, they would have been collected on the day of surgery.
Q. Of implantation surgery or on removal surgery?
A. Ahh. Removal surgery.
Q. All right. Does the timing of the inflammation related to implant, does that have any bearing upon what's -- upon the results?
A. The variable -- the variable they looked at was its relationship to pain. So if the lady's had chronic persistent pain, chronic post-surgical pain, then that had a lot to do -- if -- if the hypothesis, which it was, that inflammation was related to the pain that they were experiencing and the studies reveal that -- that chronic inflammation was not correlated with pain, that was a useful conclusion and a useful study with a hypothesis, data collection, experiments and data analysis and a conclusion.
Q. Well, if we look back at the Hill study, sir, and if you look on page 594 of the Hill study, left-handed column, bottom of the page. Do you have it?
A. Yes, sir.
Q. Says, "Subjects with voiding dysfunction

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but not pain or mesh exposure were found to have more inflammation than subjects who underwent mesh excision for pain and/or mesh erosion and those with both voiding dysfunction and pain mesh exposure. This difference may be related to timing of mesh excision in patients with only voiding dysfunction. Voiding dysfunction is usually diagnosed in the immediate post-operative period and is attributed to mid-urethral sling placement. Mesh excision often occurs sooner in these patients than in those who present with pain and/or exposure."
Did I read that correctly?
A. You did.
Q. So basically what that talks about is, that's a limitation on this subject because of the timing after surgery where the explant took place, correct?
A. Oh, no, you -- you're exactly -- you've got your facts exactly opposite. What the most inflammation is -- is after -- within the days and weeks after surgery. So you would have expected to see more inflammation after surgery, and as the scar healed, you would have expected to see inflammation decrease.
Q. Isn't -- don't the authors themselves talk

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about how -- how this is a limiting factor of their study?
A. "As a result, mesh specimens from these subjects should be expected to have higher degrees of inflammation compared to others as the healing process from the placement of the original implant would still be present." That -- that's a quote right out of their paper, the next line, in fact.
Q. But if you look at the last page, on 595, it says, it's talking about in the last -- the last column on the left-hand page, it says, "We did not have access to all of the index surgery operative reports, and therefore we relied on subject recall documented in the electronic medical record for some of our data. This limited our ability to analyze potential risk factors that may have led to increased levels of inflammation. These include the date of the index mesh placement, type of mesh utilized and the surgical approach." Correct?
A. That's right. It's not a perfect study. But it's still got very useful data.
Q. Okay. In your report starting on page 14 or starting on -- I'm sorry, paragraph 14 that you've noted, you're talking about Figure set 3, you say, "There is no demonstrated presence of nerve

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receptors." Correct?
A. That's correct.
Q. There could potentially be nerve receptors in that slide. They just weren't stained in the way that you would have done to find them, correct?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: There were no receptors found in a way that was scientifically acceptable way to stain for them and to look for them.
BY MR. MONSOUR:
Q. Right. I -- I hear you. But what I'm saying is, it's possible that there's nerve receptors in there, but what you're saying is, he just didn't stain them the right way to show us that, right?
A. And as I've --
MR. VOUDOURIS: Objection. Form. Go ahead.
THE WITNESS: And as I have said, I have no problem with there being nerve receptors throughout this tissue. It needs to be studied, it needs to be quantified, it needs to be measured, and it needs to be compared with not -- pain-free women.

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BY MR. MONSOUR:
Q. Okay. So you do believe there would probably be nerve receptors in these tissues, correct?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: I feel that there will be nerve receptors.
BY MR. MONSOUR:
Q. Okay. But what your primary criticism is, we need to look at those nerve receptors in women that don't have pain versus women that do have pain and see if there are differences that might explain it, right?
MR. VOUDOURIS: Objection. Form.
THE WITNESS: My primary issue with Dr. Iakovlev's report is he has not used the scientific method in evaluating these cases.
BY MR. MONSOUR:
Q. Okay. And how has he failed in utilizing the scientific method?
A. The scientific method is not only to make observations, which he has done, and generated hypotheses, which he has done, it is then to take the next step. The scientific method includes designing experiments, then collecting your data from these

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experiments, analyzing the data and drawing conclusions from that. What he has provided are nice, observational studies that generate useful hypotheses but do not approach a scientific study. There's no evidence of the scientific method in his work.
MR. MONSOUR: All right. Dr. McLendon, that's all the questions that I have. I will pass the witness.
MR. VOUDOURIS: Dr. McLendon, the court reporter is going to type this up for you. You have the right to read it or waive signature. I suggest that you read it, but you have to tell her that.
THE WITNESS: I like to read.
VIDEOGRAPHER: Anything further?
MR. MONSOUR: Nothing for me. Anything you guys have?
MR. VOUDOURIS: No.
VIDEOGRAPHER: This is the end of Videotape Number 3 and concludes the deposition of Roger McLendon, M.D. The time is 5:27 p.m. We are off the record.
(The deposition was concluded at 5:27 p.m.)

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(Signature reserved.)

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STATE OF NORTH CAROLINA
COUNTY OF MECKLENBURG

I, Karen K. Kidwell, RMR, CRR, CLR, in and for the State of North Carolina, do hereby certify that there came before me on Tuesday, September 29, 2015, ROGER McLENDON, M.D., who was by me duly sworn to testify to the truth and nothing but the truth of his knowledge concerning the matters in controversy in this cause; that the witness was thereupon examined under oath, the examination reduced to typewriting under my direction, and the deposition is a true record of the testimony given by the witness.
I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto or financially interested in the action.
This the 30th day of September, 2015.

_____
Karen K. Kidwell, RMR, CRR, CLR
Notary Public #19971050142

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

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ROGER MCLENDON, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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Notary Public

LAWYER'S NOTES

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